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IN RE ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY

MCL CASE NO. 634

MASTER DOCKET NO. BER-L-5064-20

CERTIFICATION OF MATTHEW R. MENDELSOHN

MATTHEW R. MENDELSOHN, of full age, certifies as follows:

- 1. I am a partner at Mazie Slater Katz & Freeman, LLC ("Mazie Slater") in Roseland, New Jersey. I respectfully submit this certification in support of Plaintiffs' Motion for Reconsideration and/or Appeal of Special Master Case Management Order No. 32. This certification is based on my personal knowledge of the facts set forth herein.
- 2. A true and accurate copy of the September 14, 2021 Case Management Conference transcript is attached as **Exhibit "A."**
- 3. A true and accurate copy of relevant portions of the deposition transcript of Roger Huff is attached as **Exhibit "B."**
- 4. A true and accurate copy of relevant portions of the deposition transcript of Victor Huynh is attached as **Exhibit "C."**

I declare under penalty of perjury that the foregoing is true and correct. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

PageID: 8997

Dated: September 18, 2024

Adam M. Slater

MAZIE SLATER KATZ & FREEMAN, LLC

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EXHIBIT A

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      IN RE: ALLERGAN BIOCELL TEXTURED :
      BREAST IMPLANT PRODUCTS LIABILITY : MCL No. 634
5
      LITIGATION
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8
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                 CASE MANAGEMENT CONFERENCE
10
11
12
    DATE: SEPTEMBER 14, 2021
13
  BEFORE: THE HONORABLE JOSEPH A. DICKSON, USMJ
14
                   THE HONORABLE RACHELLE L. HARZ, JSC
15
16
          (ALL PARTICIPANTS APPEARING REMOTELY)
17
18
19
20
21
22
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 7
    Alex Glassman, Trial Court Law Clerk
 8
    Brittany Manna, Judicial Law Clerk
 9
    Jenny Chung, Legal Assistant to Judge Dickson
10
    (Participating via telephone #8080, #4251)
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1
                    (Proceedings commenced at 11:09 a.m.)
 2
                    JUDGE HARZ: Okay. Judge Dickson, do
 3
    you want to start off?
 4
                    JUDGE DICKSON: That's fine with me.
 5
    Let's go there. So who goes first, Mr. Kelly or
 6
    Mr. Cohen?
 7
                    MR. KELLY: I'm happy to tee up the
    issue.
 8
 9
                    Essentially, there are a large number
10
    of ESI data sources at issue in this case. We have
11
    narrowed the upcoming ESI 30(b)(6) deposition to
12
    five of those at this point. One is TrackWise.
13
    got a user manual for TrackWise at the end of last
14
            We have repeatedly requested user manuals
15
    and other secondary materials as they relate to
16
    relevant repositories of ESI for years now,
17
    including the most recent conference and most recent
18
    letter. We haven't received those for any of the
19
    other four sources. It is our understanding that
20
    defendants were going to provide those.
                    That's essentially where we are.
21
22
                    JUDGE DICKSON: Mr. Cohen.
23
                    Mr. Kelly, if I can interrupt you.
24
    I'm sorry. I apologize.
25
                    Mr. Cohen, based on what I read in
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- 1 the letter and what I think Judge Harz read, too,
- 2 and I know that she has some thoughts about this, it
- 3 looks like those manuals and user programs and all
- 4 that, that you have talked about turning them over,
- 5 but you just haven't done it yet. And there's an
- 6 indication that maybe some don't exist, which is --
- 7 I would like you to explain that. If they don't
- 8 exist, why could -- how do your people work with
- 9 that software without any kind of user manual?
- 10 MR. COHEN: Right. So we have asked
- 11 about user manuals and other materials for all five
- 12 of those data sources. The one that we have a user
- 13 manual for is the CPR database, essentially the
- 14 complaints database, and we've turned that over.
- The plaintiffs have asked us for user
- 16 manuals and database schema or folder structures for
- 17 the Skype box, voicemail, and SharePoint, as you
- 18 know, and we don't have those. We've checked with a
- 19 couple of people. First of all, the technical
- 20 people didn't even understand what they were talking
- 21 about in terms of database schema and folder
- 22 structures. That wouldn't apply to a couple of
- these document types.
- 24 But users, like there was about like
- 25 28 databases all together, and most of them don't

- 1 have user manuals. Users that use them are trained
- on how to use them. And so it's not that we're
- 3 holding back on user materials that we have for
- 4 those databases. The users know how to use them,
- 5 and certainly at the 30(b)(6) deposition, the
- 6 plaintiffs can ask any questions they have about how
- 7 to use those different systems.
- JUDGE DICKSON: All right. So why
- 9 don't you have your deponents, prior to the
- 10 deposition, sign some kind of declaration about
- 11 specifically what does not exist.
- MR. COHEN: Sure, we can do that.
- MR. KELLY: That would be enough for
- 14 plaintiffs. And at this point, we would like
- 15 whatever secondary information that could help make
- 16 that deposition more efficient. We have not yet
- 17 heard before just now that these documents didn't
- 18 exist. So, if they don't, again, something in
- 19 writing with a signature on it would be helpful in
- 20 advance of the deposition enough that we can cure
- 21 any issues before the deposition.
- MS. KWUON: I would just add a
- 23 footnote to that piece. In the inquiry about
- 24 whether those documents exist, people have looked in
- 25 the appropriate places for them. There is always

- 1 the possibility, so it's hard to say, you know, when
- 2 you talk about [indiscernible word] wide, there's
- 3 always the possibility that somebody has a copy of
- 4 something, you know, squirreled away in an email
- 5 attachment or on a drive somewhere. But based on
- 6 the reasonable inquiry and research we have done,
- 7 those documents don't exist.
- And as to the schema, I think that
- 9 Max and I talked about this a little bit, it's a
- 10 document that the company doesn't have. We would
- 11 have to go to Sparta, which is the third party that
- 12 actually provides the generic tool, and then it's
- 13 customized as it relates to the way the company uses
- 14 it. So it's something, again, that the company
- doesn't have.
- 16 And I think to answer a little bit
- 17 some of the questions, as to some -- some of the
- 18 databases are also retired, so it's another reason
- 19 why something like what might be called a user's
- 20 manual doesn't appear to exist.
- JUDGE DICKSON: Well, the whole point
- is that the plaintiffs are entitled to know how this
- 23 data is used, stored, manipulated, changed,
- 24 whatever, archived, pulled out of archives. I don't
- 25 mean to tell you that you -- I know you know that.

1 But rather than having a multiday 2 deposition, let's make sure within -- it's scheduled for the 28th, correct? 3 4 MR. KELLY: Correct. 5 So I would say that JUDGE DICKSON: everything you need to get, including a declaration 6 7 of what you cannot find or what, apparently, does not exist based on a reasonable search and maybe 8 9 give a little bit of that to Mr. Kelly so he doesn't 10 have to spend an hour asking how have you searched, 11 because those are very time-consuming and annoying 12 questions in a deposition. 13 I agree, it's discovery on discovery, 14 and I get it, but this has got to move. 15 got to move, and it's time for them to have all of 16 that information, because I really want to get to 17 the substantive discovery in this case. 18 JUDGE HARZ: Can I ask a silly 19 At this deposition on September 28th, the question? individual who is being deposed, is that individual 20 21 going to have multiple screens in front of him, so 22 that if he is asked a question about box or 23 voicemail, he would be able to show during the 24 deposition what to access or where that information

would be, or are you doing this in a vacuum without

25

- 1 any computer or computer access?
- MR. COHEN: So there are two
- 3 different deponents. One deponent is speaking to
- 4 SharePoint, Skype box, and voicemail, and the other
- 5 is speaking to CPR TrackWise.
- The thing to remember about these
- 7 systems is this really is very collateral to any of
- 8 the merits about this case. These systems are not
- 9 set up just for complaints, other than the CPR
- 10 TrackWise system. So to the extent that -- and
- 11 we've questioned whether it's appropriate to have
- 12 any discovery at this stage since it is, as cases
- 13 point out, it's a discovery about discovery. There
- 14 have been no issues yet. These are just among the
- 15 28 databases that we said we were going to search
- 16 for responsive information.
- 17 So our view has been that this is all
- 18 quite premature discovery. However, we have put up
- 19 these witnesses and the thought is that they will
- 20 provide whatever background information they are
- 21 asked about. If that leads to questions, it could
- 22 yield some sources of data that we're not searching
- 23 for, we can start to reach out. But we are not in a
- 24 stage where anybody has said, Oh, we're having
- 25 trouble pulling out data or searching for data.

- 1 None of that has happened. There's no reason for --
- JUDGE HARZ: Can I just ask you a
- 3 question? You said that Skype box, voicemail, and
- 4 SharePoint weren't set up for complaints. TrackWise
- 5 was?
- 6 MR. COHEN: That is the basic
- 7 complaint system.
- JUDGE HARZ: Okay. So then the
- 9 question is going to be, in Skype box, voicemail,
- 10 and SharePoint, how does one access where complaints
- 11 would be stored? Okay. So my question is, the
- 12 person who is answering this is responding to, at
- this deposition, to that specific question about
- 14 where are complaints stored in these four systems.
- Is that person going to have access,
- 16 right then and there, with screens to show, you
- 17 know, at the deposition, how it is accessed?
- 18 Because how do you describe that? You need to show
- 19 that.
- 20 MR. COHEN: Right. So we have not
- 21 gotten to the point yet where we know even that
- there are complaints stored in any of these systems.
- 23 So what we have been focusing on is the -- first,
- the data sources most likely to have relevant
- 25 discoverable information. So our initial focus has

- 1 been on CPR TrackWise system and restoring the
- 2 email, and we have identified 38 custodians that
- 3 have email, and we've gotten from the plaintiff
- 4 their preferences as to what order we treat those
- 5 custodians in, and we're he basically following
- 6 their request.
- 7 There are going to be hundreds of
- 8 thousands, probably millions of documents in that
- 9 email which are responsive. That's where we are
- 10 starting to focus.
- JUDGE HARZ: Okay. Okay.
- MR. COHEN: We looked at these other
- 13 database sources as things that we are going to look
- into as to whether there's other discoverable
- information. That's a process and that's going to
- 16 go on. That's one of the reasons why we're saying
- 17 this discovery about discovery is premature. We're
- 18 not at a point where we found, Oh, there's a lot of
- 19 stuff in Skype that's relevant to the case.
- JUDGE HARZ: When was TrackWise put
- 21 into effect? I just forget right now.
- MR. COHEN: Janet, if you can help me
- 23 out there. I don't remember the exact date. I
- 24 think it's in our disclosure.
- JUDGE HARZ: Okay. Whenever that is.

- 1 So that's when complaints are all placed in
- 2 TrackWise, one nice, neat place. So the complaints
- 3 prior to that, you're saying, perhaps are not in
- 4 these four, you know, Skype box, voicemail,
- 5 SharePoint, but, rather, it would be in some
- 6 custodian's email somewhere. Is that what you're
- 7 saying?
- MR. COHEN: Yes. We have not gotten
- 9 to the point where we have fully investigated all 28
- 10 databases to know where everything is. The
- information that we have gained about the databases
- we have made available to the plaintiffs in the five
- 13 different disclosures that we've done in writing so
- 14 far. Those investigations of the data sources
- outside of email are continuing.
- 16 And so we -- discovery is going to go
- on for a while and we're going to be continuing to
- 18 look for anything that is responsive for this case,
- 19 and we will be continuing to meet and confer with
- 20 plaintiffs and informing them of what we find. But
- 21 I can't -- I don't know the answer right now,
- 22 sitting here, unless Janet or Melissa does, as to
- 23 whether we know of existing complaints prior to the
- 24 CPR TrackWise system where -- whether those are in
- 25 any one particular system outside of email.

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1
                    Janet, do you know anything or have
 2
    any idea on that?
 3
                                       The TrackWise is
                    MS. KWUON:
                                Sure.
 4
    managing all known complaints at this time, and for
 5
    any predecessor systems, they are transferred or
    migrated into TrackWise.
 6
 7
                    JUDGE DICKSON:
                                    That was my question.
 8
                                Yeah.
                    MS. KWUON:
                                       So it's the body
 9
    of where everything sits now. There are older
10
    versions of things in the past. So the witness is
    going to talk about TrackWise, which is what he is
11
12
    most familiar with. He has been living in that
13
    space for about a decade. And then the predecessor
14
    systems, as well, to the extent that there's
15
    information and he knows information about them.
16
                    MR. KELLY: Your Honor, just to --
17
    I'm sorry.
                Just to clarify the potentially
18
    discoverable information within the Skype, voicemail
19
    box, SharePoint system, isn't -- it isn't limited to
    complaints specifically, and it is the plaintiffs'
20
21
    understanding that all the complaints have been
22
    migrated into TrackWise from the predecessor
23
    systems.
24
                    JUDGE HARZ:
                                 Thank you.
25
                                    So then is there any
                    JUDGE DICKSON:
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- 1 decision right now that Judge Harz and I are called
- 2 upon to make? It sounds like you're going to get a
- 3 declaration or somethings under oath, signed,
- 4 regarding what you cannot find or what does not
- 5 exist, whatever the most appropriate way to say that
- 6 is, the most truthful way to say that. I know you
- 7 will do that. And then you will have it in time so
- 8 the deposition can go forward of the two deponents
- 9 on September 28th. Correct?
- 10 MR. COHEN: Yes. And just to be
- 11 clear about that, we don't have user manuals for
- 12 the -- we haven't found user manuals for the
- 13 systems, other than CPR TrackWise. Some of them,
- 14 those other questions are not applicable, like
- 15 database schema, folder structures. One or two
- 16 systems do have folder structures, but there are
- 17 reasons that they would not be helpful in locating
- 18 the documents. Would not be -- you know, nothing
- 19 that we could find and turn over in any easy manner.
- 20 That can all be explained in --
- JUDGE HARZ: Would you be able to put
- in writing to Mr. Kelly, he's asking for something
- in writing, signed, that there are no XY&Z
- 24 pertaining to Skype box, voicemail, and SharePoint?
- 25 He wants that in writing and signed. When could you

- 1 get that to him?
- 2 MR. COHEN: Subject to what Janet
- 3 said, based on our reasonable investigation, talking
- 4 with people who know the most about these systems,
- 5 what they know, find out, checking. So, yes, we
- 6 would be able to do that. And that deposition is
- 7 scheduled for the 28th, and I would think that
- 8 certainly within a few days prior to the deposition
- 9 we would be able to get that to the plaintiffs.
- JUDGE HARZ: Why don't we say by the
- 11 22nd, September 22nd.
- MR. COHEN: Yes.
- MR. KELLY: Thank you, Your Honor.
- JUDGE DICKSON: All right. So then
- 15 can we move to the organizational information?
- MR. COHEN: Excuse me. I want to
- 17 thank you. I'm the one with the conflict, so if I
- 18 might have your permission to excuse myself for the
- 19 rest of the conference. And thank you for
- 20 accommodating my schedule today.
- JUDGE DICKSON: I note that it's
- 22 11:22. If you could stay until 11:30 -- no, I'm
- 23 kidding.
- JUDGE HARZ: Good luck, Mr. Cohen,
- 25 wherever you are going.

- 1 MR. COHEN: Thank you very much. I
- 2 appreciate. Take care.
- MR. KELLY: Your Honor, if we wanted
- 4 to frontload the ESI conflicts, there is the
- 5 exemplar issues intertwined with that, although I'm
- 6 happy to defer that until later in the call.
- 7 JUDGE HARZ: The exemplar issue is on
- 8 page 6 of the September 9, 2021 letter. Basically,
- 9 I think what we're dealing with now is plaintiffs
- 10 are saying they have three -- okay. Allergan is
- 11 producing exemplar adverse event reports. There are
- 12 three issues that plaintiffs wish to follow up on,
- 13 and defendants have not responded to those inquiries
- 14 to date. I think that's --
- MR. KELLY: Yes. So the request is
- 16 for additional, you know, either fulsome answers to
- 17 those questions or additional exemplars that sort of
- 18 contain or point to or illuminate the answers to
- 19 those questions.
- JUDGE DICKSON: Was that Mr. Cohen
- 21 that was just let go who should answer that, or can
- 22 Ms. Kwuon answer that?
- MS. KWUON: I think I can answer some
- 24 of these questions.
- 25 So with regard to attachments to the

- 1 three exemplars that we provided, we are confirming
- 2 it was when we made the request that it was the full
- 3 PDF along with all the attachments. Somebody is
- 4 going back to just double check and make sure that
- 5 that was what was produced. I believe that's the
- 6 case. It looks like it. We don't seem to be
- 7 missing anything, but we're confirming that.
- As to whether or not there are
- 9 additional product complaint reports that can be
- 10 provided over the entire sequence of time, as we've
- 11 explained and I confirmed earlier, everything is
- 12 being managed through the current system and we
- 13 already kind of have moved to a discussion and
- 14 agreement with regard to extraction of fields of
- information from that to include all the complaints
- that we believe are relevant, which are the
- 17 confirmed and suspected ALCL-related cases.
- 18 And so the additional requests are --
- 19 you know, these additional add-ons that require us
- 20 to kind of stop and respond to things that are
- 21 taking away from what we're trying to do, to get the
- 22 full body of data out to plaintiffs as soon as
- 23 possibility. So the sort of the lingering ask of,
- 24 you know, can you give us one that's representative
- of XY and Z, or, you know -- this year, at some

- 1 point, I think there was even a discussion about one
- 2 per year, or something like that.
- It's difficult for us to keep kind of
- 4 down that path as we're trying to prioritize getting
- 5 the electronic extraction, which I think will be all
- of the answers, I hope, most of the answers to all
- 7 the questions that are at issue.
- MR. KELLY: Your Honor, so if I can
- 9 respond to that.
- JUDGE DICKSON: Go ahead.
- 11 MR. KELLY: The first issue is that
- 12 it sounds like we still don't have confirmation that
- 13 the exemplars that were produced are the full files.
- 14 We still don't have confirmation on that.
- Is that correct, Janet?
- MS. KWUON: No. I would say that
- when we went back and looked, it appears to be.
- 18 I've asked someone to check again. I don't know
- 19 whether counsel is thinking something is missing.
- 20 But, you know, when I come back and write to you and
- 21 say it absolutely is triple checked, that's what I
- 22 just want to make sure we're doing. We checked. It
- 23 appears to be what it's supposed to be. But I want
- 24 to get a triple check before I send that back to you
- 25 in writing.

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1
                    JUDGE HARZ: Is this in TrackWise?
 2
                    MR. KELLY: Yes.
 3
                    JUDGE HARZ: The exemplar adverse
 4
    event reports?
 5
                    MS. KWUON:
                                Yes.
 6
                    JUDGE HARZ:
                                 Is this something at the
 7
    deposition that can be delved into at that time?
 8
    Will that individual be able to say, Okay, here is
    this adverse event report, it's in TrackWise, and
 9
10
    all the documents having to do with the adverse
11
    event report are here or not here, or elsewhere?
12
    Will this person know that?
13
                    MS. KWUON: He's coming from the IT
14
    side of the program, so similar to what we might
15
    think of if we call an IT person to help with
16
    emails.
             He can answer questions regarding the
17
    technology side of it. The crossover into actual
18
    content, there may be some parts he can answer from
19
    an IT perspective, but it's different also from a
20
    business user who is, you know, actually using the
21
    communications.
22
                    JUDGE HARZ: Who would know that?
23
                    MS. KWUON: We're in the middle.
24
    what we're doing is we're actually talking to the
25
    business people who track -- who work on the
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- documents, attach the attachments, kind of click on
- 2 everything that looks like there should be an
- 3 attachment to confirm that there is an attachment
- 4 and then to compare that to what was delivered to us
- 5 as the attachment.
- 6 JUDGE HARZ: I'm just wondering is
- 7 there someone else who should be deposed who can say
- 8 whether or not the exemplar adverse event report is
- 9 everything, or where other information about that
- 10 adverse event report is in your system. That's what
- 11 I'm trying to figure out.
- MS. KWUON: So if we're able to
- 13 confirm -- one is my confirmation is that it is
- 14 complete. I'm asking someone to triple check it.
- 15 After we triple check it, I believe that that should
- 16 be, you know, as far as we can tell, you know, no
- indication that there's something missing.
- I haven't heard from counsel that
- 19 they see anything to suggest that something is
- 20 missing, or that there's a reference to a document
- 21 that actually wasn't provided as an attachment. So
- 22 what I would like to do --
- JUDGE DICKSON: Let's -- let's hear
- 24 from Mr. Kelly on -- I want to hear from Mr. Kelly
- 25 on that.

1 MS. KWUON: Sure. 2 MR. KELLY: So to be clear, I think that Ms. Kwuon is responding to our first bullet 3 4 point there, which is confirming these are the 5 complete files. Our reading of what you sent over 6 had suggested that maybe there was an external investigation report or an explanation of why an 7 investigation was not conducted, because we did not 8 9 see a writing like that or recognized something like 10 that within the exemplar that you provided, and it's 11 my understanding those are required. 12 So that was the confusion in terms of 13 that specific first bullet, the completeness issue. 14 And it might just be an disagreement about -- I 15 mean, I wouldn't be shocked if plaintiffs and 16 defendants disagree on what an adequate 17 investigation or explanation is. The second bullet relates to the 18 19 source files issue. I know that early on, you know, 20 defendants had claimed that because there were these 21 linked source files that impacted the formats in 22 which TrackWise data could be produced. Did the 23 exemplars that you guys produced, did those have 24 linked source files? Like, are these exemplars that 25 would be impacted by that issue?

1 JUDGE DICKSON: This is the question 2 I had, Mr. Kelly. You asked that question. Did you see something in the exemplars that you examined 3 4 that indicated that maybe there were links, or the 5 links were taken out? 6 MR. KELLY: There were attachments at 7 the end of the exemplars. But there was -- but I guess within exemplars. The form would end, and 8 9 there would be a cover sheet and a new document 10 within the same PDF. The question is, are those the 11 source files that defendants are talking about, or 12 have we not yet encountered an example on an 13 exemplar that has that problem with it? 14 JUDGE DICKSON: That's a more 15 specific question. Ms. Kwuon, may I please, and I'm 16 sorry to overly direct, but answer that question, if 17 you can, Ms. Kwuon. 18 MS. KWUON: It is my understanding 19 that the attachments are the source files that were completely pulled. So there's the product complaint 20 21 report and then there are all the associated 22 attachments in the PDFs and all of those were 23 completely pulled and provided to counsel. 24 JUDGE DICKSON: Okay. So the --25 MR. KELLY: The first and second

- 1 bullets then. That is very helpful. The issue then
- 2 is the third bullet, which I think is actually
- 3 something that if we handle it at the deposition, it
- 4 would be too late to handle, or it will require more
- 5 questions afterwards.
- Essentially, the issue is that, as we
- 7 discussed, complaints that were entered into past
- 8 complaint management systems have been migrated into
- 9 TrackWise.
- JUDGE DICKSON: Right.
- MR. KELLY: Those predecessor systems
- were not identical to TrackWise, or they would be
- 13 called TrackWise. So the question is: To what
- 14 extent, if any, do the data fields, the inputs and
- outputs, or even just the operating procedures for
- 16 how you -- you know, what level of detail you put
- into which field, when, whether it's a dropdown
- 18 things like that, these data fields presumably
- 19 changed over time at least to some extent.
- 20 Right now, all of the exemplars we
- 21 have are from the last six months. They were
- 22 entered into the current version of TrackWise. So
- 23 the question is -- we know now what it looks like if
- 24 you try to extract a complaint that was initially
- 25 entered into the current version of TrackWise. What

- 1 we don't know is what it looks like if you try to
- 2 pull out data that was entered into EasyTrack
- 3 [spelling unconfirmed] or into Manman, later
- 4 migrated over into TrackWise, like do those reports
- 5 come out in exactly the same format, with the same
- 6 fields, or are some of the -- we're just -- I'm
- 7 familiar with database migration like this ending
- 8 with fields getting switched, moved, or eliminated,
- 9 or added. And that's information we need, because
- 10 it's not the case that the only relevant complaints
- in this action were added into TrackWise. They were
- 12 relevant complaints in predecessor systems that have
- 13 migrated into TrackWise.
- 14 JUDGE DICKSON: I understand that.
- Ms. Kwuon, can you answer that
- 16 question?
- MS. KWUON: Those are the questions
- 18 that the witness is going to be able answer at
- 19 deposition. I think that counsel sort of set the
- 20 schedule about when they wanted the depositions
- 21 taken. These are being taken sort of first at bat
- 22 in the litigation. There are probably, you know,
- more things, for example, that we haven't produced.
- 24 That database with the actual fields yet. That is
- 25 in progress. That is going to happen after the

- 1 deposition of the witness later this month.
- And so for us, with regard to, you
- 3 know, what we are providing to the other side, it
- 4 makes sense to us that the production has been as
- 5 complete as it can be to date right now. I know
- 6 Mr. Cohen is going to provide additional information
- 7 about some of the SOPs, and the witness is going to
- 8 be able to answer these questions at his deposition.
- JUDGE DICKSON: My only concern --
- MR. KELLY: Oh, I'm sorry, Your
- 11 Honor.
- JUDGE DICKSON: Go ahead, go ahead.
- 13 And then I'll tell you what my only concern is. Go
- 14 ahead.
- MR. KELLY: My concern is just that
- 16 this is sort of an inherently written visual thing,
- 17 and it seems unlikely to me that if we asked any
- deponent, even if they're extremely familiar with a
- 19 predecessor ESI storage system platform, that they
- 20 would be able to rattle off every single data field
- 21 off the top of their head and identify which have
- 22 changed between the system they're remembering and
- 23 TrackWise.
- I think that a much easier way to
- 25 frame that conversation would be with a document

- 1 that shows what the report looks like, and say, did
- 2 this field exist, does that field exist, how are
- 3 they different across the two systems.
- JUDGE DICKSON: Well, you have that
- 5 first document. What you don't have is an exemplar
- 6 from pre-TrackWise --
- 7 MR. KELLY: Exactly.
- JUDGE DICKSON: -- or an exemplar of
- 9 TrackWise that has data that had to be migrated
- 10 over.
- MR. KELLY: Exactly.
- JUDGE DICKSON: That's what you need.
- 13 Well, that should be easy enough, I would think.
- 14 That's number one. I also agree with Judge Harz, it
- 15 seems to me it's very important to have someone,
- 16 whoever the deponent is, to have a computer in front
- of them if they need to show you at the deposition
- 18 what the difference in the fields are. Because I
- 19 get your question, I understand, and I think it's
- 20 correct. Now, I don't think this should be very
- 21 hard.
- Ms. Kwuon, can't we get them an
- 23 exemplar that has migrated information in it?
- 24 MS. KWUON: So let me go back and see
- what we can pull with regard to a pre-TrackWise

- 1 product and complaint, and I will report back to the
- 2 Court. So let me look into that.
- JUDGE DICKSON: I don't know if you
- 4 have to report back to us. If you can just put that
- 5 into -- whatever it is. I mean, it's a fair
- 6 question because -- now I'll express what my concern
- 7 is.
- 8 My concern is that we go through this
- 9 exercise, and then you produce thousands if not
- 10 millions of documents, and then as they read them
- 11 and they start to get ready to depose the custodians
- 12 or the -- or not even the custodians, but the fact
- 13 witnesses from Allergan, it turns out that there was
- 14 information that no one was able to track down
- 15 because we didn't fix this first.
- So I'm saying this for a reason,
- 17 because I am sympathetic to the discovery on
- 18 discovery issue, but this seems to be something we
- 19 need to nail down before we start massive amounts of
- 20 substantive discovery, so that we don't have to stop
- 21 that and go back and do some things again.
- 22 And I think with these simple
- 23 questions -- to me they are simple. The answers may
- 24 not be simple, but I think the questions are
- 25 simple -- we may be able to avoid that stop and go.

- 1 I mean, old war stories sometimes help. This is a
- 2 very short one.
- Patent case. We were at the end, and
- 4 then they started to fight. And I found out -- it
- 5 was a case that I took over, so it's not my problem,
- 6 but I found out that they never sat down and defined
- 7 the search terms and custodians before they produced
- 8 massive amounts of information.
- 9 If we can just -- this is akin to
- 10 that in my view. If we can make sure we know what
- 11 we're producing and how we can review it, then we
- 12 won't have a problem later.
- MR. KELLY: I know in the joint
- 14 update letter, defendants had complained there were
- 15 not MDR numbers provided. We have since sent over,
- 16 I think it was late last week, a list of MDR
- 17 exemplars that we could use if there was an issue
- 18 with selection there. So we've provided those.
- JUDGE DICKSON: Okay.
- Judge Harz, did you have anything
- 21 else on that?
- JUDGE HARZ: I see what you're
- 23 saying. Plaintiffs have not yet provided the
- 24 additional medical device reporting information they
- 25 indicated they would, so that is all done.

- 1 MR. KELLY: Yes, by letter.
- JUDGE HARZ: I have a question mark.
- 3 So I can delete that.
- 4 Okay. So just in terms of an order
- 5 that comes out of today's conference, with regard to
- 6 turning over an exemplar of an adverse event report
- 7 pre-TrackWise, when can we do that?
- MS. KWUON: How about the same
- 9 date of the -- was it the 22nd that we set?
- 10 JUDGE HARZ: Okay. Right. That is
- 11 the recertification. Okay. September 22nd, it's
- 12 going to be a pre-TrackWise -- how should I phrase
- 13 that? How should we phrase it?
- MR. KELLY: Your Honor, there were
- 15 actually multiple predecessor systems.
- JUDGE HARZ: I know.
- MR. KELLY: So I was going to say
- 18 EasyTrack and Manman.
- JUDGE HARZ: Okay. I need the
- 20 wording. I need the wording, Mr. Kelly. So by
- 21 September 22nd...
- MR. KELLY: Exemplar complaint files
- 23 from the Manman and Easytrak systems, and
- 24 corresponding to the MDR numbers plaintiffs
- 25 provided.

1 JUDGE HARZ: And EasyTrack System --2 Manman is M-A-N-M-A-N? 3 MR. KELLY: Yes. 4 JUDGE HARZ: And EasyTrack System 5 corresponding... 6 MR. KELLY: And corresponding to the 7 MDR numbers plaintiffs provided. 8 MS. KWUON: For clarification on 9 that, Your Honor, I think we can pull, you know, one 10 exemplar from each of the time periods, and use that 11 MDR number, select one from the provided the MDR 12 number. 13 JUDGE HARZ: Is that agreeable to 14 you, Mr. Kelly? 15 MR. KELLY: In full disclosure, I 16 wasn't the person who selected those MDR numbers. Ι 17 know those were the MDR numbers you were interested I don't know what the additional burden is of 18 19 producing those other exemplars. But we would want 20 all of those, is my understanding from people who 21 prepared those numbers. But I mean, if that is not 22 feasible or --23 JUDGE DICKSON: How many MDR numbers 24 were provided? 25 MR. KELLY: I think it was ten, but

- 1 let me double check that.
- MR. VESPERMANN: This is Wyatt
- 3 Vespermann with Panish. It was 13 total.
- 4 MR. KELLY: Thank you, Wyatt.
- 5 Wyatt is our MDR number selector.
- 6 MS. KWUON: To be able to do a
- 7 compare, it seems to me that one exemplar from each
- 8 of the systems enables counsel to compare. Again,
- 9 every additional thing is an additional thing. So I
- 10 think we can provide one exemplar for that MDR pool
- 11 from the various time periods.
- JUDGE HARZ: But aren't you just
- 13 pressing a button to print out 13?
- MS. KWUON: No. You know, just as we
- 15 -- I think when we started at the very beginning,
- 16 when we were going to make a production of product
- 17 complaint files and each of the attachments, there
- 18 isn't a single button. It requires, you know,
- 19 finding the particular MDR and then going and
- 20 connecting to all of the different attachments, and
- 21 then pulling each attachment and converting it into
- 22 a PDF so that it can be provided.
- It's unfortunately not as easy as
- 24 just pushing ten buttons as opposed to just one.
- JUDGE DICKSON: Well, let's do this.

- 1 Let's do three. Let's do three. And Plaintiff, you
- 2 identify the three you want her to do.
- MR. VESPERMANN: Your Honor, if I
- 4 could just chime in. This is Wyatt again with
- 5 Panish Shea & Boyle.
- 6 It's not just the migration from the
- 7 old database. There's certain adverse events, and
- 8 the way that Allergan has handled them differs, for
- 9 example, from the exemplars they provided. So if a
- 10 device is returned to Allergan, they will do a
- 11 failure analysis, and so we want an exemplar that
- 12 shows what does the failure analysis complaint look
- 13 like, or if there was someone who was in one of
- 14 their clinical studies that developed ALCL, and
- there's a couple examples of those, we want to see
- 16 how that complaint handling works.
- So it's not just the migration issue;
- 18 it does go a little bit further than that in that
- 19 not every complaint is the same. And so that's why
- 20 there were 13. It's not just migration from the old
- 21 system, but different, unique factual scenarios.
- JUDGE HARZ: Okay. I get it.
- 23 JUDGE DICKSON: It sounds more like a
- 24 substantive question than ECI, electronic data
- 25 question.

1 MS. GEIST: Your Honor, can I just 2 chime in on that, too, because I have been sitting 3 quietly. 4 From our perspective, and we will 5 comply with what Your Honor orders today, from our perspective, it is more of a substantive issue 6 7 because I think plaintiffs would have in front of them the different iterations of the adverse event 8 9 reports, right, that come from TrackWise, and before 10 that Easytrak, and before that Manman. 11 presumably, at a substantive deposition of a safety 12 person, somebody who can speak to how the company 13 records complaints as they come in, and that person 14 would answer questions about how things may have 15 changed over the various time periods. 16 So -- and again, all of the ALCL 17 complaints and suspected ALCL complaints are going 18 to be provided, all of them, for the entire time 19 period we have been discussing. So plaintiffs will have all of that and then they can put the documents 20 21 in front of them and say, okay, clearly here there's 22 a change in how the company was reporting complaint 23 information as it comes in, if that is the case. 24 So I understand. You know, again, we 25 will comply with whatever Your Honor orders, but to

- 1 me this goes more to substance, and I assume
- 2 plaintiffs will have some questions about why
- 3 certain information was reported at various times,
- 4 or not. I'm just making it up for purposes of this
- 5 argument.
- But it's more of a substantive issue.
- 7 Was there a change over time in the recording of the
- 8 complaints; and if so, why, and to what extent. And
- 9 that goes to substance.
- MR. VESPERMANN: I would push back on
- 11 that a little bit, Your Honor, because I think it is
- 12 a blurred line. There is some ESI component to this
- 13 because it's how are all these documents linked
- 14 together, how does the failure analysis link to a
- 15 CAPA?
- And so this is how their data is
- 17 managed, is that one particular event coming in to
- 18 them from a complaint-handling perspective goes down
- 19 the line and to eventually, potentially, impacting
- 20 the manufacturing specs.
- 21 And so how those things link together
- is a huge question mark right now. And it's not
- 23 necessarily substantive. It's kind of a hybrid.
- 24 There's an ESI component to how these different
- 25 systems link together.

- JUDGE DICKSON: Okay. I think if we
- 2 answer all the questions you want, we're going to be
- 3 definitely jumping into the substantive pool.
- 4 JUDGE HARZ: Well, maybe allow for
- 5 six and let the plaintiffs pick the six they want,
- 6 instead of three, so you get a broader --
- 7 MR. VESPERMANN: I'll take it, I'll
- 8 take it.
- 9 JUDGE HARZ: I don't know how much is
- 10 in -- you know, Judge Dickson and I are at a
- 11 disadvantage. Ms. Kwuon says it's a big deal, the
- 12 plaintiffs are saying it's not such a big deal.
- 13 Pick the six. You're saying that you
- 14 don't know what the different complaint files look
- like, depending upon the type of complaint. Pick
- 16 the six you want, and then for the remaining eight
- 17 or seven, you know, if you show us a need, hey,
- 18 look, look at this, this is why we need the other
- 19 seven, we can address it. Okay?
- MS. GEIST: The only thing, again,
- 21 Judge Harz, I just want to make sure it's clear, the
- 22 other seven, the ALCL-related adverse event
- 23 complaints, all of them are going to be produced.
- 24 It's just what do plaintiffs really need? What is
- 25 necessary to conduct this non-merit-based, you know,

- 1 non-substantive ESI-related deposition? And from
- our perspective, if it really is, we want to ask
- 3 somebody what is the difference between the adverse
- 4 event reporting during the Manman system, Easytrak,
- 5 TrackWise, that should be able to be accomplished
- 6 with three.
- JUDGE HARZ: Well, I think the ALCL
- 8 reporting from the plaintiffs' perspective is very,
- 9 very narrow because there's so many other words and
- 10 so many other medical conditions they would want to
- 11 see with regard to reporting, because by the time
- 12 they use the actual language of ALCL, they are
- 13 beyond the point of whether they are concerned about
- 14 suspicions having been raised.
- So I don't think the ALCL reporting,
- in and of itself, answers their questions.
- 17 MR. KELLY: It's our understanding
- 18 that defendant's ultimate production will include
- 19 confirmed ALCL cases, as well as cases with symptoms
- 20 consistent with ALCL, despite the lack of a
- 21 reference to ALCL.
- MS. GEIST: Right. We had agreed --
- MR. KELLY: And against -- I'm sorry.
- MS. GEIST: -- ALCL and suspected
- 25 ALCL. Right.

- But to Judge Harz's point, what I'm
- 2 suggesting is these are substantive questions that
- 3 will be presumably the subject of a deposition when
- 4 we get to the merits. We're just talking about an
- 5 ESI-related deposition, and I think we just need to
- 6 be clear it's limited to that.
- 7 And from what I've heard from
- 8 plaintiffs' counsel is they would like to see one
- 9 exemplar for each different system. They are all
- 10 now in one system, and they would want to see, okay,
- 11 what did it look like when the Manman system was in
- 12 place, and what did the adverse event reporting, you
- 13 know, taken in by the company look like when
- 14 Easytrak was in place.
- So they have TrackWise, and they want
- 16 an example of a report from Easytrak and Manman.
- JUDGE HARZ: Okay. So then,
- 18 Plaintiffs, why are you saying it's more than that,
- 19 that you need more than that? Why do you need more
- 20 than one from each?
- MR. VESPERMANN: Your Honor, it kind
- 22 of goes back to what I said earlier that with
- 23 respect to these complaints, these different --
- 24 there's different obligations under the regs linked
- 25 together. Right. A complaint can lead to a CAPA

- 1 analysis. And so regardless whether we're in a
- 2 particular system, whether it's TrackWise or
- 3 Easytrak, how these obligations link together have
- 4 changed over time.
- And so we just want to get a sense
- of, for example, a failure analysis complaint. When
- 7 something comes in that the device is returned to
- 8 the company, how does that process look like and how
- 9 do the systems connect. And I think there's
- 10 definitely an ESI component to that because of how
- 11 this data is stored.
- MS. GEIST: On that, Your Honor, I
- don't want to overstep Ms. Kwuon, but on that, I
- 14 think, at a minimum, we need to meet and confer
- 15 about that because this issue about a device failure
- 16 and whether or not there was a device failure
- 17 analysis, our strong suspicion is there would be a
- 18 device failure analysis when there is a, let's just
- 19 say, a mechanical failure of the device. So there's
- 20 been a rupture, or some other mechanical failure of
- 21 the device.
- The development of ALCL in a woman
- 23 who had the device implanted would be a complication
- 24 or an adverse event, but not necessarily a failure
- of the device. So if you think about a medical

- 1 device, you know, if there's a rupture, that would
- 2 be considered a failure.
- 3 So I do think on that particular
- 4 topic, I think that, you know, we should meet and
- 5 confer on that because device failure, examples of
- 6 device failure analyses are probably outside the
- 7 scope of the ALCL litigation that we're talking
- 8 about. We're talking about ruptures and other
- 9 examples of true device mechanical failure.
- JUDGE HARZ: Judge Dickson?
- JUDGE DICKSON: Well, for the limited
- 12 purpose of this deposition, I still don't see any
- 13 reason not to do what we're talking about doing,
- 14 whether it's three or six. I understand what you're
- 15 saying, Ms. Geist, but if we go down that road,
- 16 we're going to wind up pushing the deposition out
- and we're going to have briefing on whether or not
- 18 what the scope here is.
- You will not be waiving your right to
- 20 argue scope at a later date if we can just get some
- of these examples of exemplars done now so they can
- 22 at least understand what it looks like and how the
- 23 data was migrated from the earlier systems into
- 24 TrackWise, and whether or not a failure analysis of
- 25 a device will ultimately become something that they

- 1 get to look at through thousands of failure devices
- 2 we can talk about later.
- JUDGE HARZ: Okay. So we'll go back
- 4 with the three, just for the purpose of having them
- 5 go forward with the deposition? Is that your
- 6 suggestion, Judge Dickson?
- JUDGE DICKSON: No, I'm not. I don't
- 8 understand what was wrong with six. How much --
- 9 Ms. Kwuon or Ms. Geist, if they
- 10 identify six, I would say to the plaintiffs, if we
- 11 can give you six, they should be all different.
- 12 Let's not be redundant.
- MR. VESPERMANN: Absolutely,
- 14 absolutely, Your Honor. They would be very unique
- 15 factual circumstances transcending the different
- 16 databases, and that's entirely the point.
- JUDGE DICKSON: And Ms. Kwuon, I get
- it, it's going to be more work between now and then,
- 19 but how more work? I mean, can you give me some --
- 20 I mean, is it -- is it -- tell me what we're talking
- 21 about here.
- JUDGE HARZ: Its only six, it's only
- 23 these six.
- MS. KWUON: So it really depends on,
- 25 for each particular one, again, how many ancillary

- documents and datapoints are related to it. So I
- 2 can't estimate the range. Initially, when the
- 3 department was looking to this issue to pull the
- 4 1200 -- I think that was the number -- it was going
- 5 to take several months to be able to do that because
- 6 of each PDF pulled.
- 7 So what I might suggest maybe to
- 8 counsel is that if you want to give me the list of
- 9 six, perhaps rank them, we'll start with one, and
- 10 we'll try to get all six out to you by the 22nd. If
- 11 for some reason there's a great burden and timing-
- 12 related issue, we will start with one and keep you
- 13 posted whether or not we can get all the way to six.
- 14 But I would suggest --
- JUDGE HARZ: And then maybe you can
- 16 get the remaining, if you can't get all six by the
- 17 22nd, you can get all six to them by the 27th, which
- is the day before the deposition.
- MS. KWUON: Why don't you rank them
- 20 in order.
- JUDGE HARZ: Certainly get three to
- them by the 22nd, and then maybe the other three by
- 23 the 27th to alleviate the pressure.
- MS. KWUON: Thank you. That will
- 25 help. And then of course, if we can get them all

- 1 out at the same time, we will do that.
- JUDGE DICKSON: And I'd like to have
- 3 kind of a fulsome meet and confer on this. Once you
- 4 get three and you've looked at them, if you don't
- 5 need all six to get to the deposition, alert the
- 6 defendants to that.
- 7 MR. KELLY: Certainly. We will send
- 8 a ranked list very shortly.
- JUDGE HARZ: What's our next issue?
- JUDGE DICKSON: The beloved batch
- 11 records.
- JUDGE HARZ: Whoa. Oh, I have a
- 13 question about the batch records. Can I start with
- 14 a question?
- JUDGE DICKSON: You're a judge. You
- 16 can do whatever you want.
- JUDGE HARZ: A question about a
- 18 sentence. Okay. Can everyone turn to page 5 of the
- 19 joint September 9 letter. All right? I'm going to
- 20 the first full paragraph that begins with
- 21 "Identification of Biocell devices distributed in
- 22 the United States." The last sentence, I have a lot
- 23 of questions about it. Is everyone with me? I want
- 24 to wait. Is everyone okay? Can I see a nod?
- 25 COUNSEL: Yes, Your Honor.

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1
                    JUDGE HARZ:
                                It starts with the
 2
    sentence, "Nor is it feasible."
 3
                    JUDGE DICKSON: Yes.
 4
                    JUDGE HARZ: "Nor is it feasible, as
 5
    Plaintiffs contend, for Allergan to use its device
    tracking system to identify this information as that
 6
 7
    system reflects information provided by the patients
    to Allergan regarding their implanted breast implant
 8
 9
    devices, and thus does not necessarily capture every
10
    patient who was implanted with a Biocell device as
11
    not every plaintiff provides their device
12
    information to Allergan."
13
                    I have a couple questions.
14
    if it's not feasible because not every plaintiff
15
    provides their device information, that's a
16
    non sequitur. I mean, what you're basically saying
17
    is you don't believe every patient provides that
    information.
18
19
                    But my question is, does the
20
    plaintiff provide the information or does the
21
    implanting physician or the hospital, or someone
22
    else provide the information? Is it really the
    individual plaintiff?
23
24
                    MS. KWUON:
                                The information is
    typically contained within the medical records.
                                                       So
25
```

- 1 when the device is ordered, and it's different
- 2 depending upon a large practice or a small practice
- 3 or a hospital, but when the devices are ordered and
- 4 then delivered to the hospital, once we make that
- 5 delivery, we don't know what exactly happens to the
- 6 devices as to who actually receives them.
- 7 So the device, the serial number for
- 8 that finished device is generally and supposed to be
- 9 included within the medical records for tracking
- 10 purposes, and that information is generally expected
- 11 to be provided back to the company for our device
- 12 tracking. And so that's sort of like the way you
- 13 would register if you purchase a blow dryer, you
- 14 know, so that the company can let you know if
- 15 there's some kind of an issue with it.
- But that loop doesn't always happen,
- 17 and so that there isn't an ability for us to go find
- 18 and track all of that. We have to wait for that
- 19 information to come back to us so that then we can
- 20 connect those dots on our side.
- JUDGE HARZ: But some have -- I
- 22 acknowledge from this sentence that you're saying
- 23 not every time is that information provided to you.
- 24 But I'm assuming, I don't know a percentage, but why
- wouldn't that be a starting place?

1 MS. KWUON: Well, so we have the --2 JUDGE HARZ: Device tracking system, 3 yeah. 4 MS. KWUON: Sure. So when we do get 5 the information, we have the loop on any particular 6 serial number was implanted in a particular patient, 7 so we've got that information. But that doesn't 8 take us back all the way to the batch records. 9 the batch records, as we tried to explain in our 10 documentation, the system is intended to track the 11 devices as they're being manufactured, but not 12 intended to work backwards. So the backwards part 13 of it is more of a -- sometimes I call it reverse 14 engineering, which is you have to take the serial 15 numbers and then go trail back. 16 So one of the questions that came out 17 of the last hearing was, can we isolate batches 18 where devices actually were implanted in US patients 19 only. And so the answer to that is, no, we can't do 20 that at the batch record level. You have to take all the individual serial numbers and work backwards 21 22 to the batches. 23 So we were trying to convey both that 24 the serial number information we have for implants 25 is incomplete, we know that to be true, and then it

- doesn't take you to where we started, which is
- 2 isolate batches that were ultimately only delivered
- 3 to US patients only.
- 4 JUDGE HARZ: I think Judge Dickson
- 5 was reviewing some of the batch records you gave to
- 6 us as Exhibits 5. Judge Dickson, didn't you have
- 7 some questions about that?
- 8 JUDGE DICKSON: What I would like to
- 9 know is why are the batch records -- this is going
- 10 to sound like a really naive question, but why are
- 11 they so important? Because what I'm reading in the
- 12 batch records are basically quality assurance
- 13 reports. This was done, that was done, this was
- 14 done, that was done.
- Now, I confess, I did not read all
- 16 104 pages, but I read half of it. So this question
- is probably directed to the plaintiffs.
- 18 What is it that -- why do we need all
- 19 those? What's in there that is going to be critical
- 20 to your case?
- MR. SLATER: Thank you, Your Honor.
- 22 It's Adam Slater, for the record.
- To answer your question, I want to
- 24 step back one step before the manufacturing batch
- 25 records became the issue raised by the defense,

1 frankly. 2 What we asked for was the manufacturing records that would show the quality 3 4 evaluations and the outcomes of those quality 5 evaluations, and anything that they -- we don't know all the records they maintain, so we're at a bit of 6 7 a loss because we have to accept from them, from 8 Allergan, what they say they do. 9 But we need to be able to track: did 10 they do those activities that Your Honor just 11 referenced; did they actually check off that these 12 products met their specifications, number one; were 13 there any deviations; what was done in response to 14 that; and, more important -- or maybe not more 15 important, but just as important, we need to see 16 what they were doing because they should be doing some random sampling. 17 18 I think they've already acknowledged 19 they take photographs, and there may even be video, I'm not sure, but I believe they've said they're 20 21 going to be producing photographs so we're going to 22 be able to see, hopefully, whatever issues they 23 found that they documented and recorded. 24 So we're looking for the

manufacturing records that would let us know, what

25

- 1 did they do and what were the outcomes and what's
- 2 the information because, for example, there may be
- 3 issues that are shown by their manufacturing records
- 4 that weren't picked up on by Allergan or weren't
- 5 focused on that we and our experts look at and say,
- 6 this is actually really an important point of
- 7 departure where it shows why this got through or
- 8 what the problem was.
- 9 So we need the manufacturing records
- 10 for all the devices that were sold in the US because
- 11 we need to be able to track all of the manufacturing
- 12 activities and all of the manufacturing quality
- 13 activities.
- 14 Frankly, Your Honor, what you're
- 15 looking at sounds mundane and sounds like, well, why
- 16 would you need to see that people were checking
- 17 boxes, but if it turns out that they were checking
- 18 boxes and the actual finished product wasn't
- 19 complying, or in the reverse, boxes weren't being
- 20 checked so quality reviews weren't being done, that
- 21 would be very important information, and we need to
- 22 be able to confirm that up front.
- For example, if you looked in that
- 24 exemplar and you saw that a bunch of boxes weren't
- 25 checked where they're supposed to be checking the

- 1 external textured surface for certain categories of
- defects, that probably would have popped out to you
- 3 pretty strongly to say, wow, they didn't even look
- 4 at this, they didn't check it off.
- 5 So that's why we have to have a full
- 6 set of records, not a smattering, not a sampling,
- 7 and we need to be able to see that information.
- I hope that responds to your
- 9 question.
- 10 MS. GEIST: Judge, can I respond
- 11 briefly to that?
- JUDGE DICKSON: Sure.
- MS. GEIST: I feel very, very
- 14 strongly that we need to sort of reset and refocus
- on what plaintiffs' claims are, because Your Honor
- 16 said, Why do you need all this? What do you really
- 17 need? and the answer is, You don't need any
- 18 manufacturing batch records other than for the
- 19 plaintiffs who filed complaints because these are
- 20 manufacturing defect claims.
- 21 So for every single individual
- 22 plaintiff, she needs to identify in the record where
- 23 her device did not conform, was out of compliance
- 24 with the specifications for the product. That's
- 25 manufacturing defect 101. And those are the claims

- 1 in this case.
- It is not a design defect case
- 3 because that would be different and that would have
- 4 been preempted. And I hate to say preemption,
- 5 because we had very long briefing and argument on
- 6 preemption, but the plaintiffs had to argue they are
- 7 not arguing design defect because that would have
- 8 been preempted. So their claims are manufacturing
- 9 defect. They need to stick to their claims. And
- 10 what that means is every individual plaintiff, the
- 11 documents that are associated with her particular
- 12 device are the only relevant documents with respect
- 13 to manufacturing.
- JUDGE HARZ: Why is that true?
- MS. GEIST: And in addition -- in
- 16 addition -- Your Honor, I just wanted to finish my
- 17 thought. In addition to those manufacturing-related
- documents for each individual plaintiff, we will
- 19 also provide all of the CAPAs, and that's the
- 20 Corrective and Preventative Actions, that arise out
- of any non-conformities identified during the
- 22 manufacturing process.
- 23 And that's sort of a, let's just say
- 24 a global production, that's not specific to any
- 25 particular plaintiff, but a medical device company

- 1 will have a CAPA for any time they have identified a
- 2 nonconformity during the manufacturing process.
- But again, I think this is a major
- 4 dis --
- JUDGE HARZ: Mr. Slater, why is what
- 6 Ms. Geist saying not true? Why do you need for
- 7 everything and not only the plaintiffs?
- 8 MR. SLATER: Well, to begin with,
- 9 Your Honor, this is not just an individual personal
- 10 injury litigation. There's also class actions that
- 11 encompass everybody that was implanted with these
- 12 devices in the United States. So our claims aren't
- 13 limited to these individual plaintiffs, number one.
- Number two, manufacturing defect
- 15 cases can often rest on patterns that emerge over
- 16 the course of many documents across entire lots.
- 17 They may have evaluated one or two devices in the
- 18 lot that plaintiffs happened to have had the
- implants in, but there's 12 other devices or 14
- 20 other devices in that lot. When you look at the
- 21 entirety of the records, you'll see trends and
- 22 you'll see patterns.
- 23 And frankly, the last thing that
- 24 counsel said about producing the CAPAs, that sounds
- 25 great, but those come into play when they recognize

- 1 the problem. There's a very good possibility that
- 2 they didn't recognize this problem, and it's going
- 3 to be up to us to take all of their documentation
- 4 and go through that meticulously to find the signals
- 5 in those records and the indications in those
- 6 records that these problems were recurring and they
- 7 were being missed.
- I would hope that that would be the
- 9 case for Allergan's sake, that it would turn out
- 10 they didn't realize this was the problem and they
- 11 weren't catching it, because it's going to be much
- 12 more damaging to them if it turns out they knew
- there was a problem and they were ignoring it with
- 14 the textured surfaces, if it turns out that that's,
- 15 you know, based on their records and based on all
- 16 the discovery that's where the problem is, and
- 17 that's where our case is right now, obviously.
- 18 So I hope that responds to your
- 19 question.
- JUDGE HARZ: Okay. So the defendants
- 21 say, hey, class action, you're only entitled for the
- 22 class representative. You don't get, you know, the
- 23 entirety of everything that's out there. It's just
- 24 for the named class representative. That's what
- 25 they say.

- 1 MR. SLATER: I don't think that's
- 2 true because what we're looking to do is we're
- 3 attempting to establish class-wide claims and we are
- 4 representing the entire class. So, yes, there's
- 5 individual plaintiffs who have claims, but we have
- 6 the absolute right to present evidence that goes
- 7 beyond the individual plaintiff. I mean, I don't
- 8 think that the defense is suggesting if we were to
- 9 try the class case on the manufacturing defect
- 10 claims that we would be precluded from producing
- 11 manufacturing records for patients other than the
- 12 named plaintiffs.
- I mean, you can do this class action,
- 14 conceivably, for -- with, let's say, for one state
- 15 with one plaintiff. I'm trying to simplify this.
- JUDGE DICKSON: But we're not, but
- 17 we're not, and that's where I want -- I kind of want
- 18 to go there.
- How many named plaintiffs do we have?
- 20 Not representative plaintiffs, because -- don't we
- 21 have -- how many complaints have been filed? I've
- 22 lost track.
- MS. KWUON: We're at 1,040, so that's
- 24 about 900-plus in the MDL, 65 named class
- 25 plaintiffs, and then that puts it less than a

- 1 hundred in terms of any other jurisdiction. So
- there's 65. I believe it's 65 named.
- JUDGE DICKSON: 65 named class
- 4 plaintiffs, class representatives.
- MS. KWUON: Yes, out of 1,040 total.
- JUDGE DICKSON: And the rest are
- 7 individual manufacturing defect plaintiff claims.
- 8 MS. KWUON: Right.
- 9 JUDGE DICKSON: Okay. Judge Harz and
- 10 I have talked about this. For starters, for
- 11 starters, why can't we just -- and I'll get back in
- 12 a minute to Mr. Slater's answer about the batch
- 13 records, which I asked -- but for starters, why
- 14 can't we at least get all that information produced,
- 15 all that, the 1,040 produced?
- MS. GEIST: We're not disagreeing.
- JUDGE DICKSON: And I know you're
- 18 not, I know you're not, so let's at least -- I'm
- 19 sorry.
- MS. GEIST: It's a lot of paper, Your
- 21 Honor. It's like a hundred -- I think it's a
- 22 hundred pages per --
- JUDGE DICKSON: A hundred thousand, a
- 24 hundred thousand.
- MS. GEIST: -- [overtalking] process,

- 1 it's a lot of paper. I mean, this is significant.
- 2 So I would suggest a sampling, you know, any type of
- 3 sampling the plaintiffs are really looking for with
- 4 the significant volume that we already agreed to
- 5 produce, which is squarely relevant and responsive
- 6 to their manufacturing defect claims.
- JUDGE DICKSON: I get it, but what is
- 8 the schedule for produce -- let's say, in my case --
- 9 not in my case, I order that now. What's the
- 10 schedule? What is an appropriate, reasonable
- 11 schedule to get all of the batch records produced,
- 12 plus all of the CAPAs?
- Now, I just want to make sure I
- 14 understand this. You say also you would not confine
- 15 the CAPAs to the plaintiffs, that would be all
- 16 CAPAs.
- JUDGE HARZ: All CAPAs.
- MS. KWUON: Right.
- JUDGE HARZ: All CAPAs.
- MS. GEIST: Right.
- JUDGE DICKSON: I'll tell you what.
- 22 I'm not just interested in getting a lot produced
- 23 for no good reason. This whole issue of the class
- 24 and what's discoverable in class discovery, whether
- we do merits or class discovery, I don't think we've

- 1 defined. We don't have a schedule. We haven't set
- 2 forth any parameters. And when I say "I don't
- 3 think," I know we haven't. So I do want to get to
- 4 that, and I was hoping we could start the discussion
- 5 today, but I don't think we can finish it today.
- But before we get there, because
- 7 Judge Harz and I had a couple of discussions about
- 8 this, we're all in agreement that you're at least
- 9 going to produce all the batch records for the named
- 10 plaintiffs, the class representatives plus all the
- 11 individual plaintiffs. So what's the schedule to
- 12 get that done?
- MS. KWUON: Sure. So as is in the
- 14 declaration of Mr. Rodriguez, who is director of
- 15 quality at the manufacturing facility in Costa Rica,
- 16 that was the -- which was included in the most
- 17 recent one we submitted --
- JUDGE DICKSON: I saw it.
- JUDGE HARZ: We have it. We have it,
- 20 yes.
- MS. KWUON: And as you can see from
- the exemplar batch records, it is, you know, lots of
- 23 handwritten notes and depending on time, but that
- 24 estimation is six hours per batch record, to go back
- and manually pull, in many instances, from storage

- 1 the actual records requested here.
- 2 So it's estimated at six hours per.
- 3 If you take, let's say, 1,000 plaintiffs, that gets
- 4 us to 6,000 hours, 750 work days, eight hours a day,
- 5 you know, Monday through Friday. If it's one
- 6 employee full time, it could take as much as 750
- 7 days, which is three years. If it's two employees,
- 8 it's a year and a half.
- 9 I don't know if that actually is
- 10 going to hold true all the way to end, or if there's
- 11 going to be some increased efficiency. So my
- 12 suggestion might be, if we start with, let's say, I
- don't know, 10, we will pull and time and get a
- 14 better idea of what it is going to take to pull each
- one. We're going to need the finished product
- 16 serial number from plaintiffs or plaintiffs' medical
- 17 records, but we can start there. And then I think
- 18 once we get an a sampling or a test run, we can then
- 19 project out to the Court what it will take to do the
- 20 rest of the thousand.
- JUDGE HARZ: Well, no, I mean, I
- 22 think that -- listen, I don't know what the work
- 23 force is like in Costa Rica, but it would seem to me
- 24 as though, as in other litigations, the company is
- 25 going to have to hire, whether it be plaintiffs or

- defendants, very often in litigations you have to
- 2 hire other people to support what is needed in the
- 3 litigation. It would seem to me as though you would
- 4 need -- you'd maybe have to hire some people to do
- 5 this work. I mean, we can't wait two years for
- 6 these batch records for these named plaintiffs.
- 7 So I don't know how many people that
- 8 would be. Maybe it's 10, maybe it's 15, maybe it's
- 9 20. But they have to hire more people to get this
- 10 information to them.
- MS. KWUON: Right. I think I was
- 12 just trying to give an order of magnitude, but no
- 13 doubt that's correct. What I'm going to suggest is
- 14 we start with ten or a dozen, plaintiff gives us
- 15 serial numbers, we have them working, clock it, and
- then we will be able to better project what it will
- 17 take to finish one.
- 18 JUDGE HARZ: I think what Judge
- 19 Dickson and I are looking for is, aren't we, Judge,
- 20 just a date. When we -- I guess maybe we're putting
- 21 you on the spot and you have to talk to people and
- 22 you have to find out who else you're going to hire.
- 23 We need a date when the named individual plaintiffs,
- 24 whether it be in state or federal court, as well as
- the class, when their batch records can be produced.

- 1 I man, everyone agrees that has to be done, so we're
- 2 not even fighting over that. Now it's a question of
- 3 the date.
- 4 MS. KWUON: So we can do that, and I
- 5 think also the trigger point of that would be when
- 6 we have a serial number, so --
- JUDGE DICKSON: I'm sorry for
- 8 interrupting you, Ms. Kwuon. I hear you. I hear
- 9 you. But why -- can I suggest you meet and confer
- 10 with Mr. Slater or whoever Mr. Slater puts up with
- 11 you on this issue within -- and get us a joint
- 12 status letter within ten days as to -- to see -- to
- talk about who needs to do which job and how long it
- 14 will take that side to do that job, and then do --
- and then to hopefully agree. And assuming that you
- 16 don't agree, tell us, each, in the letter what your
- 17 positions are, and then Judge Harz and I will decide
- 18 how to cut the baby.
- MS. KWUON: Okay.
- JUDGE DICKSON: Great analogy, great
- 21 metaphor.
- JUDGE HARZ: Okay. So I have written
- down the number 1,040. Is that an approximate
- 24 number of batch records we're talking about right
- 25 now that we're looking for a date of production for

named individuals? Is that number correct, 1,040? 1 2 JUDGE DICKSON: That's how many plaintiffs. 3 4 JUDGE HARZ: Are my numbers right? 5 MR. SLATER: I'm not sure if that 6 included the MCL, also, Janet. I'm not sure if you 7 included the New Jersey litigation in that count. 8 I believe it did, but we MS. KWUON: 9 can go back. That's my general understanding, but 10 we can go back and check numbers. 11 JUDGE HARZ: And I think, and I might 12 be confusing my cases, aren't there also cases --13 are there cases in California on this one? 14 MS. KWUON: There are. 15 JUDGE HARZ: Yeah, okay. So then the 16 universe of cases. I think that's what we need to 17 know, right? 18 JUDGE DICKSON: Yes. 19 MS. KWUON: We'll factor that in. 20 MR. CARSON: Your Honor, this is 21 Shanon Carson. There are also many cases that are 22 subject to a tolling agreement between the parties, 23 so I think that needs to be factored into this 24 discussion. 25 JUDGE HARZ: How many? How many?

1 MR. CARSON: Dave, do you know the 2 exact number? MR. STANLEY: Yeah, I do. 3 Yes. 4 Good morning, everybody. David 5 Stanley from Reed Smith for defendants. 6 We have, if you count the foreign 7 claimants, we have over 6,000 tolled claimants, so 8 -- and that would complicate things significantly if 9 we were factoring those in. So I think we should 10 probably try to stick to what we have on file, at 11 least at this point. 12 JUDGE HARZ: Did you say foreign 13 claimants? 14 MR. STANLEY: Yeah, there are a 15 number of citizens of South Korea who have entered 16 into a tolling agreement. We haven't necessarily 17 agreed that if -- once the tolling agreement expires 18 that we would -- that we would allow them to come 19 into the United States to file claims without 20 objection. But at least at this point, those claims 21 are tolled. 22 If you take those out of the 23 equation, I would have to go back and check my 24 charts to see, but out of the 6- or 7,000 tolled 25 claimants, probably over half of them are from South

1 Korea. 2 JUDGE HARZ: And the country of 3 implant was? 4 MR. STANLEY: I don't understand your 5 -- you mean -- oh, no. South Korea. So these are South Korean plaintiffs who were implanted in South 6 7 Korea. 8 JUDGE HARZ: Okay. Thank you. 9 MS. GEIST: And again, I just wanted 10 to note, the vast majority, I think, of the 11 plaintiffs who have filed and then the named 12 plaintiffs, the vast majority of plaintiffs are 13 women who have not been diagnosed with ALCL. 14 that's a very --15 JUDGE HARZ: Right. 16 MS. GEIST: -- rare condition, so 17 some consideration might be given to the differences among the plaintiffs. 18 19 JUDGE HARZ: Thank you. 20 JUDGE DICKSON: In terms of the class 21 actions, are there -- I went back and I was looking at Judge Martinotti's opinion, and he deals with a 22 23 medical monitoring class. Are there any other 24 proposed causes of action in the complaint that were

not brought up on motion, other than medical

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1 monitoring, for a class action? 2 MR. CARSON: Yes, Your Honor. There are extensive causes of actions that are pleaded in 3 4 the class action complaint, including causes of 5 actions for breach of warranty, and causes of action 6 for violation of state consumer protection statutes, 7 and there -- it's a complaint that, if I remember 8 correctly, is over 1200 pages, most of which is 9 causes of action individually listed for each 10 jurisdiction. And so there -- there is a lot there. 11 JUDGE DICKSON: I really -- Judge 12 Harz and I started this conversation. And Judge, I 13 apologize. The more I thought about it, the more I 14 realized how well I wanted to focus, so I haven't had a chance to tell this to you to get your take on 15 16 So you can slap me back as much as you need to. it. 17 But before I'm going to be 18 comfortable making a final decision on what batch 19 records or any other manufacturing records that we 20 haven't even discussed, if there are any, should be 21 produced in the federal action, I need the parties to do what they normally do, and that's tell me in a 22 23 joint discovery plan what discovery -- what's 24 relevant discovery for these causes of action,

because there are issues as to --

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- I mean, normally, we all know you
- 2 don't take discovery from putative claimants, and so
- 3 -- and I think Ms. Geist has made that point and I
- 4 agreed that is a point to be considered. But I
- 5 heard what Mr. Slater said today, too. But I need
- 6 to know how this discovery that you're seeking
- 7 relates to the causes of action in the class, the
- 8 class action cases. Not in the individual cases.
- 9 That's easy.
- MR. CARSON: Your Honor --
- JUDGE DICKSON: But in the -- but in
- 12 the individual cases, we've already told you you
- 13 have to turn over all the batch records for the
- 14 individuals, so that's not really an issue. I'm
- 15 talking about the class action.
- MR. SLATER: I think what might be
- 17 getting lost, Your Honor, is that there's a
- 18 manufacturing defect claim obviously in the class
- 19 actions, which is the basis for the remedy of
- 20 medical monitoring for states that consider it to be
- 21 a remedy as opposed to a --
- JUDGE DICKSON: Okay, okay. So
- 23 that's what I assume, but I need for the parties to
- 24 relate the discovery that would be irrelevant for
- 25 class discovery. And that's the other issue. We

- 1 haven't talked whether we're going to do class
- 2 discovery and merits discovery at the same time, or
- 3 whether we're going to do class discovery first.
- 4 And I know sometimes it's almost impossible to
- 5 separate them, or at least it's difficult. And we
- 6 need to talk about that, I think.
- 7 MR. CARSON: Your Honor --
- JUDGE DICKSON: At least from my
- 9 perspective, we have to. We have to do both.
- I'm sorry, Shanon. I didn't mean --
- MR. CARSON: No, I was going to say I
- 12 completely agree, Your Honor. This wasn't teed up
- 13 as an issue for today's conference, but we will meet
- 14 and confer with defense counsel and do what exactly
- what you're suggesting, and I think defense counsel
- 16 would agree with this, as well, and tee up these
- 17 class discovery issues for the next conference.
- 18 JUDGE DICKSON: Ms. Geist, you agree
- 19 with that, right?
- MS. GEIST: I'm sorry, Judge. I was
- 21 nodding. Yes, of course, we're happy to meet and
- 22 confer and discuss it, and we can certainly discuss
- 23 it at the next conference.
- 24 JUDGE DICKSON: So, for this
- 25 conference, though, and then there's one other issue

- 1 Judge Harz, that you and I talked about because I
- 2 still don't understand why we cannot find out. I
- 3 understand what you're telling me, defense counsel,
- 4 as to why it's impossible -- not impossible -- I
- 5 think "feasible" was part of that sentence that was
- 6 contained in the paragraph where you were, I think,
- 7 pushing back on the idea of determining which --
- 8 connecting the batch records for the products that
- 9 were shipped into the United States.
- 10 And I get that from that perspective,
- 11 because it's all on paper and you have to reverse
- 12 engineer and everything, but let me try another idea
- 13 which I mentioned to Judge Harz.
- 14 Why can't you go to the Allergan
- 15 sales people, department, whatever we want to call
- 16 it? I mean, those are the ones that ultimately
- 17 would have sold the devices in the United States,
- 18 the United States Allergan sales people, assuming
- 19 they have a sales department for every country.
- 20 Even if they don't, why would not the sales
- 21 department have records on what they sold in the
- 22 United States over the last 30 years.
- MR. SLATER: Your Honor, it's -- I
- 24 think it might not even -- I think sales would know,
- 25 obviously, but there's actually an arm of the

- 1 company, I would assume, that is a production arm,
- 2 and I'm using "production" generically, that is
- 3 involved in overseeing all of the shipping.
- If they send a product anywhere, they
- 5 track it. They have paper or they have electronic,
- 6 and they know exactly every device where it went.
- 7 They have to know that. So they know every device
- 8 that went to the United States. They have to.
- JUDGE DICKSON: Well, Mr. Slater, you
- 10 should understand that I want to know this because
- 11 I'm trying to determine whether or not we can reduce
- 12 the magnitude of some of the discovery. You are
- 13 going to continue to argue, I assume, that you want
- 14 everything that Costa Rica touched.
- MR. SLATER: No, no. What we
- 16 actually said in the letter was this. What we want
- is the records for the lots from which product was
- 18 sold into the United States. We have stepped back
- 19 from our position, and we thought it was a
- 20 significant compromise, from all of the
- 21 manufacturing records in the plant.
- What we've said is we'll accept the
- 23 lots from which product was sold to the US, because
- they've told you, Well, we don't know what every
- 25 single product, exactly, if it was in plants or not,

- 1 who it went to, but they know if products went from
- 2 Lot A to the US. If they sold three from that lot
- 3 to the US and 17 to France, we are asking for that
- 4 lot.
- 5 That way it makes it simpler for them
- 6 to identify the lots. And we've taken a big step
- 7 back from what our initial ask was.
- JUDGE DICKSON: Ms. Kwuon.
- 9 MS. KWUON: Sure. So I guess to
- 10 answer the Court's question about the reverse
- 11 engineering, whether your --
- JUDGE DICKSON: I agreed with it. I
- 13 understood it. I'm not really asking why is that
- 14 so. I got it. I'm saying, why can't we do what
- 15 Mr. Slater just said? In other words, forget Costa
- 16 Rica, or trying to get the information out of Costa
- 17 Rica.
- 18 MS. KWUON: So it's two-fold. One is
- 19 we have to start with the issue of whether or not
- 20 it's relevant to the case, and we start pulling
- 21 batch records for non-plaintiffs. We have our
- 22 class-related argument that we're going to address,
- 23 it sounds like at the next hearing, with more
- 24 specificity. And then we have the inordinate amount
- of burden related to this particular kind of going

- 1 any broader than what we're doing here with regard
- 2 to the plaintiffs.
- 3 So just as we're going to get more
- 4 information to provide to the Court about how long
- 5 it's going to take even to do the 1,000-plus -- and
- 6 again, that early estimate was six hours per record
- 7 that we're pulling and tracing -- as it relates to
- 8 the batch records, the design history records, as
- 9 you can imagine, the records that follow start to
- 10 then trail off and become individual records to that
- 11 particular finished product.
- 12 So there isn't a commonality of a
- common set of records that is going to apply all the
- 14 way to finished product. So it still is a very
- 15 manual process.
- When we're talking about manually
- 17 pulling records for batches and for devices that
- 18 didn't even enter the United States, we are talking
- 19 about three quarters of the production, devices that
- 20 were sent out globally and not in the US, we're
- 21 talking about multiplying all of those things, the
- 22 six hours per batch record, the number of hours it's
- 23 going to take to pull that manual pull, the
- 24 exponential level that has -- and we've looked --
- 25 never been ordered is above and beyond what we're

- 1 talking about here, which are the plaintiffs that
- 2 are at issue.
- 3 So what we would like to do is what
- 4 the Court is suggesting, is start with a set, run
- 5 through the whole process, get very precise metrics
- 6 about time and burden. We can extrapolate from
- 7 there what it will take to do over a thousand
- 8 plaintiffs and their batch records, and then it
- 9 makes sense, at least to us, to then pause as we
- 10 address the scope of discovery relative to putative
- 11 class plaintiffs.
- JUDGE DICKSON: Okay. But I'm
- interested in getting an answer to Mr. Slater's
- 14 question. And maybe you're right, maybe it comes in
- 15 the discussion about the scope, but I think -- I
- 16 want to know how we can track what was brought into
- 17 the United States, from my perspective, which I can
- 18 reduce the scope for you, which Mr. Slater is
- 19 apparently agreeing to do. Well, I shouldn't say
- 20 "apparently." Which he has flat-out agreed to do.
- MS. KWUON: From what entered the
- 22 United States was implanted in a US patient, the
- 23 tracking on that is with the serial number. So you
- 24 have to take --
- JUDGE DICKSON: I think you're -- I

- don't mean to interrupt you, but I think you're
- 2 narrowing it down right now to the named plaintiffs.
- 3 Right?
- 4 MS. KWUON: No, no, to all -- to all
- 5 implants that entered into the United States with
- 6 the intention. So what happens is that --
- JUDGE DICKSON: So you're saying
- 8 Mr. Slater is wrong and there's not some corporate
- 9 department who knows what was brought into the
- 10 United States. Whether they were implanted or not.
- 11 They could be sitting on shelves. But I'm talking
- 12 about devices that come to the United States.
- MS. KWUON: Okay. So they sit in a
- 14 distribution center, and then when there is an order
- 15 for a particular type and size, those breast
- 16 implants are then sent to that location. So the
- 17 distribution center does know what it is sending
- 18 when it receives orders.
- 19 It does not have information there
- 20 that links it back to batch records. To actually
- 21 link it back to batch records, you have to go down
- 22 to the serial number, just like we would need to get
- from the plaintiffs, and then go backwards to find
- 24 the batch number.
- 25 So there isn't a way to take the

- 1 batch data of 280,000 batches and say, Oh, these are
- 2 the ones that have less bound devices and these are
- only global. Instead, you have to start with that
- 4 serial number order in that distribution center and
- 5 go backwards to see what batch that belongs to.
- 6 JUDGE DICKSON: Okay. I understand
- 7 what you're saying now. So you can identify what
- 8 products were shipped into the United States, but
- 9 you will not be able to link that with a batch
- 10 record until we have -- I got it.
- MR. SLATER: Your Honor, just to be
- 12 clear because I don't want to have misled Your
- 13 Honor, if I did.
- 14 What we're asking for -- and I see
- where you're going, and we'll obviously abide by
- 16 whatever you do.
- We're asking for the lots from which
- 18 the product went to the US. Not just the product
- 19 that went to the US, not just the records for those
- 20 devices, but for the full lots, because that's
- 21 actually easier for them to produce. If they know
- 22 they shipped any product from a particular lot to
- the US, that lot would be captured and they don't
- 24 have to do this production they're talking about.
- 25 And I also will tell you, and maybe

- 1 what it's time for Allergan to do is start producing
- 2 their distribution center records and show us --
- 3 have some transparency on what these records look
- 4 like because I would be stunned if the distribution
- 5 center records that say these 50 devices went to the
- 6 US doesn't list the serial numbers and everything
- 7 else.
- 8 They have to be able to track forward
- 9 and back, and we're asking them to track forward
- 10 now. They said they can't reverse engineer, that
- 11 they can't do that. They don't need to do that.
- 12 What they need to do is know what they sent and
- 13 where they sent it to, and they know that, and they
- 14 know it in the distribution records.
- If their records don't reflect the
- 16 serial numbers of what product got sent to the
- 17 United States someplace, then they're saying there's
- 18 no way to link the products that went to the US to
- 19 where it was manufactured. That would be
- impossible, and the FDA would be very interested in
- 21 that.
- MS. KWUON: I feel like we're
- 23 speaking in circles. I'm saying that the serial
- 24 numbers can't be identified from when they are
- 25 distributed. I'm just saying that having that

- 1 serial number doesn't take us back to being able to
- 2 better sort identify the batches. You have to take
- 3 the serial number, trace, pull these batch record
- 4 documents that has been provided to the Court to get
- 5 you back to the batch. This isn't a shortcut in
- 6 trying to partition or parse out the different
- 7 batches. That was the only part I'm trying to --
- JUDGE DICKSON: Okay. Here's what
- 9 I'd like, here's what I'd like.
- 10 Mr. Slater, can you give me a letter
- 11 that outlines where you are now, and I don't mean to
- 12 suggest that you're changing, but I think you did
- 13 say you reduced your --
- 14 MR. SLATER: I think it's in the
- 15 letter we submitted, frankly, Your Honor.
- JUDGE DICKSON: Which letter?
- MR. SLATER: The January. It should
- 18 be in there. At least it was when I wrote it.
- JUDGE HARZ: It's on page 2, the
- 20 second to last paragraph: "Plaintiffs offered to
- 21 compromise their request, without prejudice to
- 22 future requests, to accept the manufacturing records
- 23 for all lots and batches from which devices were
- 24 sold into the United States. Defendants rejected
- 25 this position out of hand."

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1
                    It's on page 2, second to last
 2
    paragraph.
 3
                                    Uh-huh.
                    JUDGE DICKSON:
 4
                                I'm sorry. Does Allergan
                    All right.
 5
    tell me in here why they are rejecting that out of
 6
    hand?
 7
                    MS. KWUON:
                                Yes.
                                      So if we go back to
 8
    -- so plaintiffs went from all global to --
 9
                    JUDGE DICKSON:
                                         Did you tell me
                                    No.
10
    -- did you actually respond to that in this letter?
11
    Because I'm looking at the letter, but apparently
12
    I'm having trouble with a brain fart trying to
13
    figure out which --
14
                    MS. KWUON: We did on multiple
15
    fronts. So the first section on class was based on
16
    what is the appropriate scope of discovery.
17
    second part of it was a discussion about how the
18
    exemplar batch records, the hundred pages, is
19
    representative of what you're going to extrapolate
    back to 273,000 batches.
20
21
                    JUDGE DICKSON:
                                    Right.
22
                    MS. KWUON:
                                Reducing down to US might
23
    reduce the piece count by tens of millions, but it
24
    doesn't reduce the amount of work in tracing back to
25
    the batches.
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1
                    And then the last part of our
 2
    argument there had to do with what we're able to do
    and the scope of what we're talking about with
 3
 4
    regard to the 1,000-plus plaintiffs at hand here.
 5
                    So we did address it in the letter.
 6
                    JUDGE DICKSON:
                                    I'm going to --
 7
                    MS. GEIST:
                                Judge, can I just say one
 8
    thing? One thing.
 9
                    JUDGE DICKSON: Yes, sure.
10
                    MS. GEIST:
                                I think we did address on
11
    multiple fronts, as Ms. Kwuon just articulated, at a
12
    rock bottom, at rock bottom we're talking about over
13
    a million devices sold in the United States.
14
    that just translates. What does that translate
15
    into? It's 130 million pages. So I think, at rock
16
    bottom, that is our argument, why we are saying no,
17
    because it is wildly overbroad, it is not relevant,
18
    and we have already agreed to turn over the
19
    manufacturing batch records for over 1,000
20
    plaintiffs, which will be at least 6,000 hours.
21
                    So I would just say the sheer number,
22
    130 million pages, I think more than demonstrates
23
    the overbreadth of this argument on behalf of
24
    plaintiffs.
25
                    JUDGE DICKSON: All right. So Judge
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- 1 Harz and I will continue to discuss it, unless she's
- 2 ready to rule right now.
- JUDGE HARZ: We will discuss. We
- 4 will discuss.
- JUDGE DICKSON: So let's move on to
- 6 the organization tables.
- JUDGE HARZ: When are the CAPAs going
- 8 to be produced?
- 9 MS. KWUON: Those will be produced, I
- 10 would say, by like the second week of October.
- JUDGE HARZ: Let's give it a date.
- MS. KWUON: Let me look at my
- 13 calendar.
- JUDGE HARZ: October 15th?
- MS. KWUON: October 15th. Thank you.
- 16 MS. GEIST: Your Honor, I have the
- 17 organizational information.
- JUDGE DICKSON: Okay.
- MS. GEIST: I did want to note, Your
- 20 Honor, I had designated 90 minutes or an hour and a
- 21 half for our conference, which I think is what we
- 22 had agreed upon, and with apologies, I have a hard
- 23 stop right before 1:00.
- JUDGE DICKSON: That's all right.
- 25 Let's see if we can chainsaw this.

1 Your Honor, I can state MS. GEIST: 2 very briefly, and I'm sure plaintiffs will respond. 3 Very briefly, we've provided quite a bit of 4 organizational information by the company. I think 5 Your Honor stated earlier, let's get to the merits discovery. This is not merits discovery. 6 This is 7 organizational information. We have provided quite a bit in two separate letters to the plaintiffs, 8 which we referred to and included in the index. 9 10 I'm not sure what the focus is. 11 have -- as a reminder to the Court and to the 12 parties, there was a stipulation put in place in 13 this litigation as to the proper parties, the proper 14 named defendants, so a lot of this focused on 15 corporate organization and structure seems to be a 16 little far along from the real issues. 17 We have provided and we will continue 18 to provide any organizational charts that the 19 company has and maintains. We have communicated to plaintiffs that historically Allergan and its 20 21 predecessors did not and were not required to keep organizational charts. There is not a central 22 23 location or a database for organizational charts. 24 I counted in preparation for today's

conference at least 119 organizational charts that

25

- 1 we produced for Allergan, for McGhan and Inamed, the
- 2 predecessor companies, and that this organizational
- 3 information covered many, many different
- 4 departments, including regulatory, marketing,
- 5 medical, safety, quality assurance.
- So we have produced what we have. We
- 7 will continue to produce or give custodial files if
- 8 we find any other organizational charts. But our
- 9 position is there shouldn't be -- we shouldn't need
- 10 to do anymore. We can only produce what we have.
- 11 And I harken back to our last
- 12 argument about, you know, plaintiffs' request that
- 13 we put together charts of information. There's no
- 14 obligation to do that, similar with the
- organizational charts. We have produced quite a bit
- and we have complied with our obligations.
- So that's our position.
- JUDGE DICKSON: Let's hear from
- 19 plaintiff.
- MR. SLATER: I will cut to the chase.
- 21 We're going to -- we would like to
- send a 30(b)(6) notice, take a deposition of
- 23 corporate representatives. I'm sure the Court is
- 24 weary, as we are, with lawyer letters going back and
- 25 forth with bits and pieces of the story being put

- 1 together. I'm sure the Court has never seen such
- 2 difficulty in understanding the organization of a
- 3 defendant or defendants.
- 4 So we would like to end the
- 5 letter-writing campaign. We would like to depose a
- 6 30(b)(6) witness and put this issue to bed because,
- 7 from our perspective, we need this to have the
- 8 context, to understand the documents, to understand
- 9 who is who, to understand who matters, to know what
- 10 things mean, to understand which companies were
- 11 doing what, what departments did what. Then we can,
- when we go into the regular depositions of actual
- 13 fact custodians, we're not going to have to waste
- 14 deposition time asking organizational questions.
- So that's what we ask for, Your
- 16 Honor. We would just like to move to the deposition
- 17 and put this issue behind us.
- 18 MS. GEIST: And we strongly disagree,
- 19 probably not surprisingly. I do think that's
- 20 backwards. I don't think I've ever been involved in
- 21 a litigation of this type where you had to give a
- 22 30(b)(6) up front on corporate organization. At a
- 23 minimum, it comes to the defense via interrogatory.
- 24 I'm very familiar with that. That might be an
- 25 appropriate vehicle.

- But as the documents are produced,
- 2 typically, it becomes very clear when you look at
- 3 the documents. Which, again, there's 115
- 4 organizational charts in our production already.
- 5 There's a lot of information there. But as the
- 6 documents continue to be produced, it becomes very
- 7 clear, you know, who are the critical people
- 8 involved in the decision-making, what were their
- 9 roles over various time periods. It's all very
- 10 evident from the documents. And then plaintiffs can
- 11 ask their questions at the appropriate merit
- 12 deposition.
- I don't know how we would possibly
- 14 put up a 30(b)(6) witness on all of these topics for
- 15 the last, you know, however number of years we're
- 16 talking about. It would seem to be virtually
- impossible. And again, Your Honor, I'm not aware of
- anybody having to do this, and if this information
- 19 cannot be gleaned from what we've already provided,
- 20 I think the appropriate vehicle would be
- 21 interrogatories.
- I think we had talked about
- 23 interrogatories at our last conference or our
- 24 conference in July when a similar type information
- was being requested. I think the default is always

- 1 "We're going to take a deposition," and why don't we
- 2 really get to the merits and stop, you know, with
- 3 the sideshow of a 30(b)(6) deposition every time we
- 4 have a dispute.
- 5 MS. LENZE: Your Honor, so, if I may,
- 6 one of the reasons -- well, let me start with this.
- 7 To use a phrase that has been proffered by Ms. Kwuon
- 8 earlier today, the information we have requires us
- 9 to reverse engineer to find who the players are.
- 10 And the Court, Your Honors, have
- 11 already ordered in CMO 2 the defendants to provide
- 12 information about the departments and the divisions
- 13 for all defendants, and there are major gaps in what
- 14 they've produced.
- For example, the information they
- 16 have produced in their, I believe it was, July 20th
- 17 letter only provided information from 2020 with
- 18 respect to the Allergan defendants. With respect to
- 19 McGhan, it was only for one year; I believe '99.
- 20 With respect to Inamed, maybe 2002, 2003, to 2004.
- 21 But there are major holes in even the structure to
- 22 begin with.
- 23 And then their production of
- 24 organizational charts is similarly as lacking. We
- 25 are given one year of maybe global medical, for

- 1 example. Then maybe that's from 2010. We've also
- 2 seen maybe something from 2012 of one department,
- 3 but we don't even know where to plug that department
- 4 in because we have no original chart from that year
- 5 to understand the structure.
- And the documents that they've
- 7 provided, including the 38 custodial names,
- 8 similarly leave us with kind of these gaps and
- 9 questions. There's only seven individuals on that
- 10 list of the 38 that were a part of the companies
- 11 prior to 2006, and 2006 was when Allergan got
- 12 involved. But McGhan has existed, you know, back
- 13 from 1974.
- 14 And so, you know, we request this
- information really about who was in charge of these
- departments, what were the departments like in any
- 17 given year, and who ran these departments. Even in
- 18 the 38 custodial names, we're given lots of
- 19 directors, we're given lots of -- we have no
- 20 understanding of who to go to or who to put up,
- 21 even, as our potential custodians because we don't
- 22 know what the structure is, we don't know the names.
- 23 And obviously, it goes to what they knew and when
- 24 they knew it.
- Obviously, one of the points that

- 1 Allergan makes in their letter and was just made
- 2 here is that, you know, this information about
- 3 predecessors is tangential, but this information,
- 4 plaintiffs' position is that this information is
- 5 really critical. The first presence of ALCL in the
- 6 literature was even back in the '90s.
- 7 So what the company was doing back in
- 8 the '90s and who was responsible for doing it is
- 9 really at the core of our case, and so we are, at
- 10 our most basic, requesting a years chart, really, of
- 11 what the structure looked like for any one of the
- 12 given companies and who was at the head of those
- 13 divisions.
- 14 JUDGE HARZ: I think -- Judge
- 15 Dickson?
- JUDGE DICKSON: No, go ahead.
- JUDGE HARZ: I think we should have a
- 18 deposition. The questions is, I'm not sure one
- 19 person can provide the information that is being
- 20 requested. I understand what is being requested. I
- 21 also agree it's not a tangential issue. I circled
- that in the letter that it's not tangential.
- 23 So I think what would be best --
- 24 actually, it's kind of already been done, but I
- 25 don't know if the plaintiffs want to write a letter

- 1 indicating the information they want. I mean, I
- 2 hear names. McGhan, Inamed. I hear time frames.
- 3 If you want to write a letter saying that you want a
- 4 person with best knowledge to provide information
- 5 regarding X, Y, and Z from such companies from this
- 6 period of time to such period of time, because then
- 7 defense counsel may want to produce two or three
- 8 different individuals to respond to the scope of
- 9 that deposition focus.
- MR. SLATER: Your Honor, we can even
- 11 -- that's a great idea. I think we can even go one
- 12 better to try to save a step. If we get a week, we
- 13 can serve the dep notice within a week. That way it
- 14 will be spelled out exactly what we're looking for.
- 15 And we can even copy the Court if you want when we
- 16 submit it to the defense so you can --
- JUDGE HARZ: Yes. Copy the Court, as
- 18 well. In terms of scheduling the dep, I mean, once
- 19 you serve the notice, I think defense counsel will
- 20 have to determine who can respond to what. It may
- 21 be two people, it may be four people. I don't know.
- But I agree, I'm kind of done with
- 23 this whole issue, and I think we -- plaintiffs
- 24 wanted to do the dep to begin with. I said no. We
- 25 were working -- and Judge Dickson said no. Now it's

- 1 just do that.
- MS. GEIST: Your Honor, my only --
- 3 again, I don't mean to reargue again and again. My
- 4 only, I guess, request or at least for
- 5 consideration, is why are interrogatories not the
- 6 appropriate vehicle for this type of --
- JUDGE HARZ: We're not going to get
- 8 the information unless someone is deposed with the
- 9 knowledge. Interrogatories is more writing. We're
- 10 done. We're done with -- we have to move forward.
- 11 Do the deposition. Let an individual answer who did
- 12 what when and who was in charge when, because the
- 13 plaintiffs need this so that they can move forward
- 14 to know what custodial records they need. We all
- 15 know this. We have to move this case. Okay?
- 16 That's why. Interrogatories aren't going to give
- 17 anything more than all the other papers. They want
- 18 to move to questions.
- JUDGE DICKSON: So, Ms. Lenze, or
- 20 Mr. Slater, or both of you, the dep notice, and not
- 21 just to reiterate it, has to specifically go for
- those gaps.
- MR. SLATER: They will.
- MS. GEIST: Do we have a time? I
- 25 mean, you know what, Your Honors, what I would

- 1 suggest is we will see the deposition notice, I
- 2 suspect we will have some objections to scope and
- 3 time period.
- JUDGE DICKSON: Well, we'll do it the
- 5 old-fashioned way. You will respond to the dep
- 6 notice and if you don't meet and confer to work it
- 7 out, then you'll write a letter and I'll --
- JUDGE HARZ: Yeah.
- JUDGE DICKSON: Or Judge Harz will.
- JUDGE HARZ: Yeah. Why would there
- 11 be objections as to who would have knowledge as to
- 12 organizational information of the company?
- JUDGE DICKSON: I think Ms. Geist was
- 14 talking about how far back they want to go, and to
- 15 what department they might want to.
- I'm sorry. Ms. Geist, why don't you
- 17 explain.
- MS. GEIST: No, that was exactly --
- 19 that was my thinking exactly. Depending on the
- 20 departments we're talking about and --
- JUDGE HARZ: Okay. Mr. Slater, how
- 22 far back is the deposition notice going to go?
- MR. SLATER: I think it's probably
- 24 going to go back quite a ways in terms of the
- 25 corporate relationships and identifying the people

- in the departments that would make -- be the most
- 2 significant to the issues in the case, and we're
- 3 going to try to figure that out. And we're happy,
- 4 once we serve the deposition notice, for the defense
- 5 to say, Hey, you know, this is what you really need,
- 6 and that is what you really need, and they can help
- 7 us with some vocabulary.
- 8 Some of these companies go back to
- 9 the '80s, but we're obviously not going to ask for
- 10 the name of every person that was in a certain
- 11 department in 1988, because that's going to be hard
- 12 to get. We're going to figure out which are the
- 13 most salient features of the organizations that we
- 14 need, and as we move forward, we will probably need
- 15 more granular information. And I think that these
- 16 questions from Your Honor and Judge Dickson help us
- 17 to know that we do need to focus and to make sure
- 18 what we're asking for in this deposition that we can
- 19 defend it.
- MS. GEIST: That sounds fine.
- 21 Keeping in mind the date of the label change,
- 22 keeping in mind when this new disease sort of came
- 23 into --
- JUDGE HARZ: Oh, speaking of the
- label change, what are we going to do with regard to

- 1 providing information as to when certain things --
- 2 like particular dates. Remember, there was a whole
- 3 issue. Plaintiffs wanted to know specific dates
- 4 for --
- 5 MR. SLATER: For approval and in use
- 6 dates.
- JUDGE HARZ: Thank you.
- What are we doing with that?
- 9 MS. GEIST: We had a very lengthy
- 10 discussion about that, Your Honor, in July, and I
- 11 don't think we had a resolution. I know Your Honor
- 12 said many times, forget about the charts, because I
- 13 highlighted it in the transcript, forget about the
- 14 charts.
- JUDGE HARZ: Just give the
- 16 information, yeah.
- MS. GEIST: Out opposition was, you
- 18 know, we're not creating charts since we're --
- JUDGE HARZ: Well, everyone is going
- 20 to need to know that. You need to know that, the
- 21 Court needs to know that, plaintiffs need to know
- 22 that. So I just don't want to leave that hanging
- 23 because it's something that is going to come up
- 24 again.
- So are you meeting and conferring

- 1 about this? What are we doing with the issue?
- MR. SLATER: Your Honor, frankly, I
- 3 think that we are at the point where we are -- and
- 4 I'm almost embarrassed to have to say this because
- 5 I've never had such issues on such foundational
- 6 basic things.
- I don't know why, for example,
- 8 defense counsel doesn't want to provide a chart.
- 9 Whether they provide it in a list, on an abacus, I
- 10 would think that they would want an organized
- 11 document so everybody can refer to it when we get to
- 12 trial, and say, Everybody, we gave you this
- information, you know when these things were in use,
- 14 so don't tell us you don't know.
- So I would like to -- whether it's a
- 16 chart or a list, they don't want to give it to us at
- 17 all, just like they don't want to give us
- 18 organization information.
- So I'm embarrassed to say we have to
- 20 depose a witness, and as the deposition goes on, put
- 21 each document in front of the witness, and say, When
- 22 was this approved? When was it in use? and then
- 23 write it down and fill our own chart out and hand it
- 24 to the witness at the end of the deposition, and
- 25 say, That's what you told us, correct? Now we have

- our chart, because it's the only other way to go at
- 2 this point. And I can tell you, if there's -- I
- don't think there's any question in Your Honor's
- 4 mind about how important this information is. I
- 5 mean, it's clear --
- JUDGE HARZ: Everyone needs this
- 7 information. Okay. So I'm just asking, let me ask
- 8 defense, what is your plan with regard to responding
- 9 to this request, the approval and in use dates?
- MS. GEIST: So I think Mr. Slater and
- 11 I should talk about it. I am only aware of having
- 12 to do this once before, and that was pretrial, so it
- 13 was late in the game, when the discovery was done
- 14 and the parties were deciding what evidence they
- 15 wanted to use at trial.
- JUDGE HARZ: How would you do the
- 17 depositions --
- 18 MS. GEIST: They were done, they were
- done, Judge, because usually a revision date at the
- 20 bottom of communication pieces with physicians, and
- 21 directly to women, you know, patient-focused
- 22 communications.
- JUDGE HARZ: Like, for example, if
- 24 you don't know when a particular brochure was used,
- 25 if you don't know when particular marketing material

- 1 was used, how do you ask questions about it at a
- 2 deposition?
- MR. SLATER: You don't, Judge. What
- 4 you do is you guess. And I can tell you in the MCL
- 5 in front of you with Ethicon, all of this was done.
- 6 We got all the charts. Riker Danzig produced them
- 7 all. And it made that litigation, as Your Honor
- 8 knows, seamless on this issue. There was never a
- 9 question. We know when everything was in use and we
- 10 don't ever have to come back and argue, and we don't
- 11 have questions, we don't have open ended --
- JUDGE HARZ: How can they give it to
- 13 you? Who would you depose to get the information?
- MR. SLATER: I guess they'll have to
- 15 put up a witness or witnesses, and they'll have to
- 16 go through this -- we'll have to do somebody on the
- 17 DFUs, somebody on the patient brochures, someone on
- the sales and marketing, and someone on the
- 19 professional education. That's probably the way it
- 20 will have to happen because they don't want to just
- 21 cooperate and give us the information.
- MS. GEIST: It's not a question of
- 23 cooperation. First of all, you're asking us to
- 24 create work product. We're not obligated to do
- 25 that. Second, in the DFUs, like the IFUs, there

- 1 typically is an effective or revision date. We have
- 2 found it to be very, very close to impossible to
- 3 give any, you know, this was the beginning date and
- 4 this was the end date when this communication piece
- 5 was out. And we discussed that complexity and
- 6 challenge before, you and I, Adam.
- 7 MR. SLATER: Right. And I would say,
- 8 Melissa, when we did this with Bard, you gave us --
- 9 you gave me, when I asked for this, when I became
- 10 liaison counsel for the Bard litigation in Bergen
- 11 County, you got the DFU dates, I believe the patient
- 12 brochure dates. You -- I think you got me marketing
- 13 dates. And on professional education, Bard said,
- 14 "We don't know," and that was it. They didn't know.
- 15 And then we knew that those can't be used against us
- 16 by Bard where they would come in and say, Well, this
- 17 was used with this doctor, now here's the date. So
- 18 at least everyone was on a level playing field.
- MS. GEIST: Right, which was very,
- 20 very late. It was very, very late in that
- 21 litigation, pretrial. So why don't we --
- MR. SLATER: No, it was actually --
- 23 well, I don't want to argue with you. Let's --
- MS. GEIST: Hold on. We have an
- 25 order from Judge Dickson relating to the marketing

- 1 and communication pieces. Why don't we get that
- 2 pushed out and get that produced to plaintiffs, and
- 3 then we can meet and confer on what that looks like.
- 4 MR. SLATER: Well, what this is going
- 5 to do is it just pushes the ball so far down the
- 6 road.
- 7 For example, when the documents come
- 8 in to us and we start seeing emails -- make up a
- 9 date -- January 1st, 2004, and someone says to
- 10 someone, you know, we have a problem with XYZ. We
- 11 then need to be able to look at what were they
- 12 telling doctors immediately after that, what were
- 13 they saying in their marketing, what were they
- 14 saying in the DFU. We need to be able to match up
- and triangulate internal documents with what they
- 16 were saying to the world.
- 17 And that's one of the -- not just --
- 18 so we don't need just this information for the
- 19 implanting doctors and learned intermediaries who
- 20 were critical; we also have to be able to know the
- 21 story. What were they saying to the world and what
- 22 did they know internally, and the only way to know
- 23 that is by knowing the in use dates.
- I find it hard to imagine the company
- doesn't know when things went into use because

- 1 that's something that is tracked very carefully by
- 2 the marketing and sales people.
- MS. GEIST: No, it's typically not.
- 4 MR. SLATER: If they don't know, they
- 5 don't know.
- 6 MS. GEIST: But I am going to
- 7 apologize again. I have to run a meeting at 1 p.m.
- 8 We are way over our time. Maybe we need to --
- 9 JUDGE HARZ: I want to revisit this
- 10 approval and in use dates, because if you can't
- 11 agree, we'll just schedule a depositions around it.
- 12 Okay? But you talk, you figure out what you want to
- 13 do, and we can --
- When is our next meeting, Judge
- 15 Dickson?
- 16 JUDGE DICKSON: I don't think we have
- 17 one scheduled.
- 18 JUDGE HARZ: Okay. And are we going
- 19 to send out an order regarding these particular
- 20 dates what we agreed to today for all counsel?
- JUDGE DICKSON: Oh, yeah.
- JUDGE HARZ: Okay. And when would
- 23 you like to meet again, so we can let Ms. Geist go.
- 24 MR. SLATER: Your Honor, I was going
- to suggest that maybe we start to schedule the

- 1 hearings if a little shorter time frames and start
- 2 to do this more often, just because then the issues
- 3 will be fresh and we can get closure on the issues
- 4 in a little bit more of a shorter turnaround, if
- 5 that's okay with --
- JUDGE HARZ: Okay. So today is
- 7 September -- what's today?
- 8 MR. KELLY: 14th.
- JUDGE HARZ: 14th. Just not the
- 10 first week in October, please.
- 11 MS. GEIST: We have October 19
- 12 scheduled for the next conference.
- MR. SLATER: What about September 30,
- 14 Your Honor?
- JUDGE DICKSON: I can do September
- 16 30th.
- JUDGE HARZ: I can do September 30.
- MS. KWUON: I'm traveling on the
- 19 30th.
- JUDGE HARZ: Who is that? I'm sorry.
- MS. KWUON: It's Janet Kwuon for
- 22 Allergan. I'm traveling on the 30th.
- MR. SLATER: We would be very
- 24 concerned about pushing it beyond that, so --
- JUDGE HARZ: October 1st?

- 1 MR. SLATER: That's fine with me.
 2 MS. GEIST: I can't do it on October
 - 3 1st. I'm sorry.
- JUDGE HARZ: Wednesday, the 29th? I
- 5 have another big thing in the morning. I could do
- 6 it after 1:00.
- 7 MR. SLATER: That's fine.
- 8 MS. KWUON: I'm sorry. The 29th and
- 9 30th are both travel days for me.
- JUDGE HARZ: Okay. How about the
- 11 28th?
- MR. KELLY: I have a deposition that
- 13 day, Your Honor.
- 14 MS. GEIST: Can we do it after the
- 15 deposition, Judge? What about that first week in
- 16 October.
- JUDGE HARZ: The first week in
- 18 October, I'm away.
- MR. SLATER: Can we just do it on the
- 20 30th? I understand Janet is going to be traveling,
- 21 but some of these issues we just need to be able to
- 22 get closure from the perspective of everybody, I
- 23 would think. I'm just concerned about pushing it
- 24 beyond that week.
- MS. GEIST: I think you realize that

```
1
    Janet is our main contact person on all things
 2
    discovery.
 3
                    MS. KWUON:
                                Sorry for everybody else.
 4
                    MR. KELLY: Have we proposed the 27th
 5
    yet?
 6
                    MR. SLATER: That's fine.
 7
                    MR. KELLY: I realize it's less than
 8
    two weeks, but it's better than waiting a month.
 9
                    JUDGE HARZ: I'm okay the 27th.
10
                    JUDGE DICKSON:
                                    I'm good.
11
                    JUDGE HARZ: Okay.
                                        What time?
12
                    MS. KWUON: Can we do it again at
13
    11:00 Eastern?
14
                    JUDGE HARZ: 11:00 Eastern.
15
                    JUDGE DICKSON:
                                    Okay.
16
                                Your Honors, we just have
                    MS. LENZE:
17
    one other issue on the agenda today, and
18
    understanding Allergan's response from September
19
    10th indicated with respect to the RFPs --
20
                    MR. SLATER: Jen, can I just
21
    interrupt you one second.
22
                    MS. LENZE: Yeah, sure.
23
                    MR. SLATER: I apologize. I have a
24
    deposition of an expert to take in four minutes.
    Can I be excused?
25
```

```
1
                    JUDGE DICKSON: Ms. Geist has to go.
 2
                    Ms. Geist, can you make somebody else
 3
    the host?
 4
                    MS. GEIST: I don't know, Judge. If
 5
    I hit end, I don't know.
 6
                    MS. LENZE: And all I was going to
 7
    ask was just for a date certain that Allergan
 8
    supplements, that's it, in 30 seconds.
 9
                    MS. KWUON: I can't give you a date
10
    like on the spot, but I'll get back to you today.
11
                    MS. LENZE:
                                Okay.
12
                    MS. KWUON: I think then we're done.
13
                    JUDGE HARZ: Thank you, everybody.
14
    Okay. Bye.
15
16
             (Conference adjourned at 12:57 p.m.)
17
18
19
20
21
22
23
24
25
```

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1	CERTIFICATION
2	
3	I, CONSTANCE E. PERKS, CCR, CRR, CRC, RSA,
4	a Certified Realtime Court Reporter and Notary
5	Public in and for the State of New Jersey, do hereby
6	certify the foregoing to be prepared in full
7	compliance with the current Transcript Format for
8	Judicial Proceedings, and a true and accurate
9	transcript to the best of my knowledge and ability.
10	
11	
12	Constances & Mark Carcer as
13	
14	Constance E. Perks, CCR, CRR, CRC, RSA
15	Notary Public and Certified Court
16	Reporter of the State of New Jersey
17	NJ CCR License #30XI00142900
18	Dated: September 15, 2021
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Case 2:19-md-02921-BRM-LDW Document 516-2 Filed 09/18/24 Page 105 of 113 PageID: 9100

EXHIBIT B

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1
                 UNITED STATES DISTRICT COURT
                 DISTRICT OF NEW JERSEY
 2
                 CASE NO. 2:19-MD-02921 (BRM)(ESK)
 3
 4
 5
    IN RE: ALLERGAN BIOCELL TEXTURED
    BREAST IMPLANT PRODUCTS LIABILITY
 6
    LITIGATION
                                              MDL NO. 2921
 7
    This Document Relates To:
 8
                                           : CONFIDENTIAL
    All Cases
 9
10
                       SEPTEMBER 28, 2021
11
12
13
                        TRANSCRIPT of the videotaped
14
    30(b)(6) deposition testimony of ROGER A. HUFF, held
15
    remotely via Zoom on the above-referenced date and
16
    commencing at 9:01 a.m. PST, as stenographically
17
    reported by Constance E. Perks, CRR, CCR, CRC, RSA,
18
    a Federally-Approved Certified Realtime Reporter and
19
    Notary Public, NJ CCR License #300XI0142900.
20
21
22
23
24
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            ph 877.370.3377 | fax 917.591.5672
25
                       deps@golkow.com
```

```
1
            relevant ESI sources.
 2
    BY MR. KELLY:
 3
             Ο.
                   And I'm going to list them and
 4
    make sure that you understand that you're here
 5
    to speak about them today.
 6
                    Does that make sense, Mr. Huff?
 7
                    MS. KWUON: Can I ask to see the
            document all the way through, and then
 8
 9
             the date on it?
10
                    MR. KELLY: Sure.
11
                    And it keeps going into the --
12
             there's an attachment of the original
13
             30(b)(6) notice.
14
                    MS. KWUON: And can we go off
15
             the record for just a second?
16
                    MR. KELLY: We have a pending
17
            question, actually.
18
                    MS. KWUON: Oh. What's the
19
            pending question? Sorry.
    BY MR. KELLY:
20
21
            Ο.
                Do you understand that you
22
    are -- I can phrase it again. Sorry.
23
                    I'm going to list the four
24
    potentially relevant ESI sources that are
25
    within the scope of your deposition. Those
```

```
are Box, voicemail, SharePoint, and Skype.
 1
 2
                    Is that your understanding of
 3
    the scope of this deposition?
 4
             Α.
                    Yes.
 5
             Q.
                    Thank you.
 6
                    MS. KWUON:
                                 Okay. Thanks, Max.
 7
                    And can we go off the record for
 8
             a second?
 9
                    MR. KELLY:
                                 Sure.
10
                    THE VIDEOGRAPHER: The time is
11
             9:18.
                    We are off the record.
12
                    (A recess was taken.)
13
                    THE VIDEOGRAPHER: The time is
             9:22.
14
                   We are back on the record.
15
    BY MR. KELLY:
16
                    So just before the break, we
             Ο.
17
    clarified that the four data sources at issue
18
    in this deposition are Box, SharePoint,
19
    voicemail, and Skype. Is that right?
20
                    That's correct.
21
             Ο.
                    And you have been designated
22
    today as a corporate representative to give
    testimony on behalf of the company.
23
24
                    Do you know what that means?
25
             Α.
                    I believe so.
```

```
privileged information.
 1
 2
                    But you can answer beyond that.
 3
                    THE WITNESS:
                                  No.
 4
    BY MR. KELLY:
 5
             Q.
                    So you -- you don't know what
 6
    steps, if any, Allergan took to preserve
 7
    documents relevant to this litigation?
 8
             Α.
                    That's correct. I do not.
 9
             Ο.
                    Okay. Are you aware of the
10
    settings or policies with regard to any of the
11
    four data sources we're here to talk about
12
    today - that's Box, SharePoint, voicemail, and
    Skype - are you aware of policies or settings
13
14
    changing for any of those four sources in
15
    connection with the litigation hold?
16
                    MS. KWUON: Objection as to
17
             form; compound, vague and ambiguous,
             lacks foundation.
18
19
                    But you can answer the question.
20
                    THE WITNESS: If you could help
21
             me with understanding the two parts.
22
             Am I aware of policies, or am I aware
23
             of settings being changed?
24
    BY MR. KELLY:
25
             Q.
                    Its only the latter.
                                           Let
```

EXHIBIT C

```
1
                 UNITED STATES DISTRICT COURT
 2
                 DISTRICT OF NEW JERSEY
                 CASE NO. 2:19-MD-02921 (BRM)(ESK)
 3
 4
    IN RE: ALLERGAN BIOCELL TEXTURED
    BREAST IMPLANT PRODUCTS LIABILITY
 6
    LITIGATION
                                              MDL NO. 2921
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    This Document Relates To:
                                           : CONFIDENTIAL
    All Cases
 9
10
                       SEPTEMBER 28, 2021
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13
                        TRANSCRIPT of the videotaped
14
    30(b)(6) deposition testimony of VICTOR HUYNH, held
15
    remotely via Zoom on the above-referenced date and
16
    commencing at 1:08 p.m. PST, as stenographically
17
    reported by Constance E. Perks, CRR, CCR, CRC, RSA,
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    a Federally-Approved Certified Realtime Reporter and
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    Notary Public, NJ CCR License #300XI0142900.
20
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1	that adverse incident reports,
2	investigation, or reporting.
3	So you have our designation of
4	what the witness is going to cover.
5	MR. BUCHANAN: Yeah, and I
6	thought it was co-extensive with topic
7	1 and subcategory of b. Is there
8	something you're carving out there,
9	because I believe we're limited on
10	technical topics here.
11	MR. COHEN: Yeah, so it
12	certainly it what he's going to
13	testify to is certainly part of what's
14	in 1.b., but he is testifying with
15	regard to a particular database, and
16	that's not to say that's the only
17	document out there that has to do with
18	adverse incidents, investigations, or
19	reporting.
20	But reporting in that particular
21	database is what he's designated for.
22	MR. BUCHANAN: Fair enough. So
23	you're scoping just so we're on the
24	same page, you're scoping and limiting
25	him specifically to TrackWise,

```
1
             correct?
 2
                    MR. COHEN: Correct.
 3
                    MR. BUCHANAN:
                                   Okay. But no
 4
             other concern with regard to the
 5
             topics and the introductory paragraph
             of 1?
 6
 7
                    MR. COHEN: No other objection.
 8
                    MR. BUCHANAN: That's fine.
 9
             Thank you.
10
    BY MR. BUCHANAN:
                    Moving on to 2, sir: "The
11
             0.
12
    Allergan Defendants' information files,
13
    including currently maintained computer files,
14
    as well as historical, archival, back-up, and
15
    legacy computer files, whether in current or
16
    historic media or formats, such as digital
17
    evidence that may be used to support claims or
    defenses."
18
19
                    Do you see that, sir?
20
             Α.
                    I do, yeah.
21
                    Are you prepared to testify with
             Ο.
22
    regard to that topic as it relates to
23
    TrackWise?
24
                    MR. COHEN: I'm going to --
25
                    THE WITNESS:
                                   I --
```